

7. Instructions For Use

Idacio® Vial Kit

Single use components and medicine vial (adalimumab) for subcutaneous injection
40 mg/0.8 mL

Note: Images for illustration purposes only.

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Read carefully these entire instructions before using your Idacio Vial Kit.

Important Information

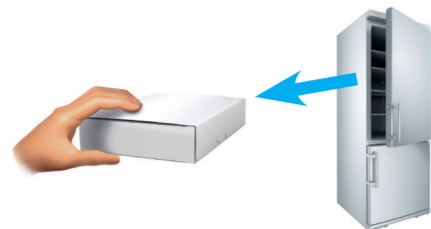
- Only use Idacio Vial Kit if your healthcare professional has trained you how to use it correctly.
- Idacio Vial Kit is for single use only.
- Children are not allowed to inject themselves and injection must be done by a trained adult.
- Keep all components of the Idacio Vial Kit and the sharps disposal container out of reach and sight of children.
- Do not shake the syringe or the vial. Shaking can cause damage.
- Contact your healthcare professional or pharmacist if you have question or need support.

Storage information

- Store the Idacio Vial Kit in its original box to protect it from light.
- Store the Idacio Vial Kit in a refrigerator between 2°C to 8°C.
- If needed, for example when traveling, the Idacio Vial Kit can be stored at room temperature for up to 14 days.

Step 1 Gather supplies and check for damages

1.1 Remove the Idacio Vial Kit from the refrigerator.



1.2 Leave the kit at room temperature for at least 30 minutes to allow the medicine to warm up. Injecting cold medicine may be painful.



Warning: Do not warm the kit any other way, such as in a microwave, hot water, or direct sunlight.

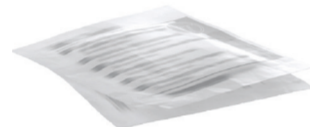
1.3 Open the kit and take out all components and put them on a clean, dry, flat surface. Check components to make sure that the packaging and the content are not damaged.



Vial



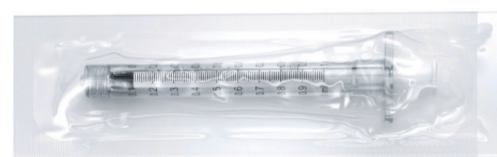
Vial adapter



Alcohol pads



Needle



Syringe

Warning: Do not use if damaged.

1.4 You will also need following supplies that are not included in the kit:

- A clean cotton ball or gauze, and
- A sharps container (see section 7.2).

Open your sharps container so it is ready.



1.5 Check your records for injection dates and injection sites to figure out the injection site for this session.



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Step 2 Prepare Vial

2.1 Wash your hands with soap, water and dry them well.



Warning: Gloves do not replace the need for washing hands.

2.2 Check the label on the vial for Idacio and expiration date.



Warning: Do not use the vial if:

- The name on the vial is not Idacio.
- The expiration date on the vial has passed.

2.3 Check the liquid to make sure that: The liquid is clear, colorless, and free of particles.



Warning: Do not use the vial if the liquid is cloudy, colored or has particles or flakes in it.

2.4 Gently remove the yellow cap from the vial.

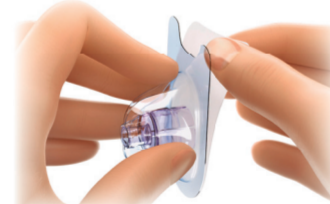


2.5 Wipe the entire vial top with an alcohol pad and throw the pad away.



Warning: Do not touch the top of the vial after cleaning.

2.6 Peel off the paper from the vial adapter packaging without taking the vial adaptor out of its packaging.



Warning: Do not touch the vial adapter.

2.7 With the vial adapter still in its packaging, push the vial adapter onto the vial top until it snaps in place.



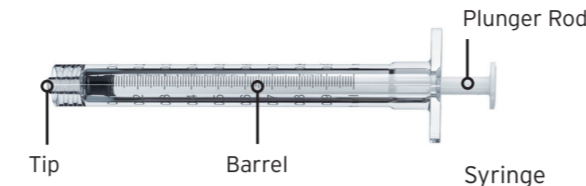
2.8 Hold the vial and lift the packaging off. To ensure the adapter remains on top of the vial, hold the packaging by the outer rim.



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Step 3 Prepare Syringe



3.1 Peel open the syringe packaging and grab the syringe by the barrel.



Warning: Do not touch the syringe tip.

3.2 Hold the vial adapter, insert the syringe tip into it and screw to connect.



3.3 Turn the vial upside down so it is vertical with the syringe still attached.



3.4 Keep the vial and syringe vertical and slowly pull the prescribed dose.



Warning: If the plunger rod is pulled completely out, throw away the syringe. Do not try to reinsert it and use a new kit.

3.5 Slowly push the plunger rod all the way in to push the medicine back into the vial. This is to remove any air gaps or bubbles.



Again slowly pull the plunger out to the prescribed dose and stop.

If you still see air gaps or bubbles at the tip of the syringe, repeat this step until air gaps or bubbles are gone. Do not shake the syringe.

Warning: Do not use the syringe if there is a large amount of air in the syringe.

3.6 Turn over the vial and syringe, firmly hold the vial adapter and unscrew the syringe from the vial adapter.



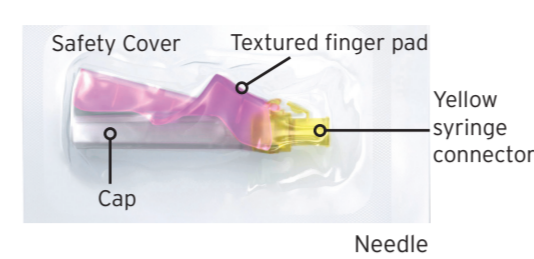
3.7 Place the syringe on a clean, flat surface.

Warning: Do not touch the syringe tip.
Warning: Do not throw the vial away.

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Step 4 Prepare Needle



4.1 Peel open the needle packaging to uncover the yellow syringe connector.



Warning: Do not take the needle out of its packaging.
Warning: Do not touch the yellow connector.

4.2 Insert the syringe tip into the yellow syringe connector and screw to connect.



4.3 Pull the needle packaging off.

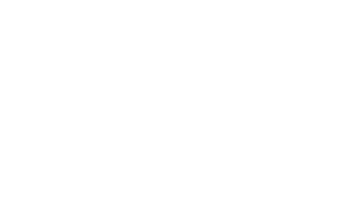
Warning: Do not remove the clear needle cap.

4.4 Pull back the pink needle safety cover toward the syringe.



Warning: Do not detach the pink needle safety cover from the yellow connector.

4.5 Place the syringe on a clean, flat surface.



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Step 5 Prepare Injection

5.1 Choose an injection site on:

- Top of the thighs
- or
- Lower stomach area (inject at least 5 centimeters away from the belly button).



Choose a different injection site (at least 2.5 centimeters away from the previous injection site) each time to reduce redness, irritation or other skin problems.

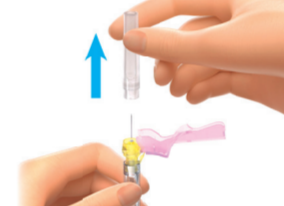
Warning: Do not inject into an area that is sore (tender), bruised, red, hard, scarred or where there are stretch marks.

5.2 Clean the injection site with an alcohol pad and throw the pad away.



Warning: Do not blow on or touch the injection site after cleaning.

5.3 Remove the clear needle cap by pulling it straight off and throw it away.



Warning: Do not try to put the needle cap back on the needle.

5.4 Hold the syringe like a pencil with the pink needle safety cover pointing up



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Step 6 Give Injection

6.1 With the other hand, gently pinch a fold of cleaned skin and maintain it.



Warning: Do not touch where you aim to inject.

6.2 With a quick, short motion, push the needle into the skin at an angle of 45°.

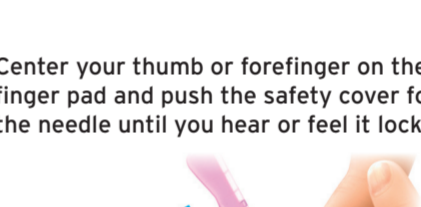


Note: With experience, you will find the angle (between 45° and 90°) that is most comfortable for you and the child.

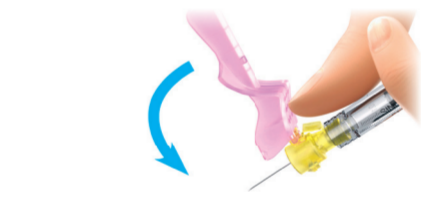
6.3 Gently push the white plunger rod all the way down until the syringe is empty.



6.4 Remove the needle from the skin, being careful to pull it out at the same angle that it was inserted. Then release the pinched skin.



6.5 Center your thumb or forefinger on the textured finger pad and push the safety cover forward over the needle until you hear or feel it locks.



6.6 The needle is now covered and is safe. It can now be thrown away in the sharps container.

Warning: Call your healthcare professional if you did not inject the full dose.

6.7 If there is blood or liquid on the injection site, gently press a clean cotton ball or gauze on the skin for 10 seconds.



Warning: Do not rub the injection site.

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Step 7 Record injection and dispose components

7.1 Now that you have completed your injection, update your record with:

- the injection site
- the date
- any issue you had
- the lot number (on vial label).



7.2 Throw away the used syringe with the protected needle and the vial with attached vial adapter into a sharps container.



Warning: Keep your sharps disposal container out of the reach of children.

Warning: Do not keep any unused medicine.

Warning: Do not throw away the syringe or the vial in your household trash.

If you do not have a sharps disposal container, you may use a household container that is:

- Made of a heavy-duty plastic;
- Can be closed with a tight-fitting, puncture-resistant lid; that will keep sharps from coming out,
- Upright and stable during use,
- Leak-resistant and
- Properly labeled to warn of hazardous waste inside the container.

7.3 When your sharps disposal container is almost full, you will need to follow your local guidelines for the right way to dispose of your sharps disposal container.

Warning: Do not recycle your used sharps disposal container.

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Information for the patient

Idacio®



FRESENIUS KABI

40 mg/0.8 mL solution for injection for paediatric use

adalimumab

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you child starts using this medicine because it contains important information.

- Keep this leaflet. You may need to read it again.
- Your doctor will also give you a patient reminder card, which contains important safety information that you need to be aware of before your child is given Idacio and during treatment with Idacio. Keep this patient reminder card with you or your child during treatment and for 4 months after you (or your child's) last injection of Idacio.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child's.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet (see section 4).

What is in this leaflet

- What Idacio is and what it is used for
- What you need to know before your child uses Idacio
- How to use Idacio
- Possible side effects
- How to store Idacio
- Contents of the pack and other information
- Instructions for use

1. What Idacio is and what it is used for

Idacio contains the active substance adalimumab, a medicine that acts on your body's immune (defence) system.

Idacio is intended for the treatment of the following inflammatory diseases:

- polyarticular juvenile idiopathic arthritis
- enthesitis-related arthritis
- paediatric plaque psoriasis
- adolescent hidradenitis suppurativa
- paediatric Crohn's disease
- paediatric uveitis

The active ingredient in Idacio, adalimumab, is a monoclonal antibody. Monoclonal antibodies are proteins that attach to a specific target in the body.

The target of adalimumab is another protein called tumour necrosis factor (TNFα), which is present at increased levels in the inflammatory diseases listed above. By attaching to TNFα, Idacio blocks its action and reduces the inflammation in these diseases.

Polvarticular juvenile idiopathic arthritis and enthesitis-related arthritis

Polvarticular juvenile idiopathic arthritis and enthesitis-related arthritis are inflammatory diseases of the joints that usually first appear in childhood.

Idacio is used to treat polyarticular juvenile idiopathic arthritis and enthesitis-related arthritis. Your child may first be given other disease-modifying medicines, such as methotrexate. If these medicines do not work well enough, your child will be given Idacio to treat his/her polyarticular juvenile idiopathic arthritis or enthesitis-related arthritis.

Paediatric plaque psoriasis

Plaque psoriasis is a skin condition that causes red, flaky, crusty patches of skin covered with silvery scales. Plaque psoriasis can also affect the nails, causing them to crumble, become thickened and lift away from the nail bed which can be painful. Psoriasis is believed to be caused by a problem with the body's immune system that leads to an increased production of skin cells.

Idacio is used to treat severe plaque psoriasis in children and adolescents aged 4 to 17 years for whom medicines applied to the skin and treatment with UV light have either not worked very well or are not suitable.

Adolescent hidradenitis suppurativa

Hidradenitis suppurativa (sometimes called acne inversa) is a long-term and often painful inflammatory skin disease. Symptoms may include tender nodules (lumps) and abscesses (boils) that may leak pus. It most commonly affects specific areas of the skin, such as under the breasts, the armpits, inner thighs, groin and buttocks. Scarring may also occur in affected areas.

Idacio is used to treat hidradenitis suppurativa in adolescents from 12 years of age. Idacio can reduce the number of nodules and abscesses you have, and the pain that is often associated with the disease. You may first be given other medicines. If these medicines do not work well enough, you will be given Idacio.

Paediatric Crohn's disease

Crohn's disease is an inflammatory disease of the gut.

Idacio is indicated for the treatment of Crohn's disease in children aged 6 to 17 years. Your child may first be given other medicines. If these medicines do not work well enough, your child will be given Idacio to reduce the signs and symptoms of his/her disease.

Paediatric uveitis

Non-infectious uveitis is an inflammatory disease affecting certain parts of the eye. The inflammation may lead to a decrease of vision and/or the presence of floaters in the eye (black dots or wispy lines that move across the field of vision). Idacio works by reducing this inflammation.

Idacio is used to treat children from 2 years of age with chronic non-infectious uveitis with inflammation affecting the front of the eye.

2. What you need to know before your child uses Idacio

Do not use Idacio

- if your child is allergic to adalimumab or any of the other ingredients of this medicine (listed in section 6).
- if your child has a severe infection, including tuberculosis, sepsis (blood poisoning) or other opportunistic infections (unusual infections associated with a weakened immune system). It is important that you tell your doctor if your child has symptoms of infections, e.g. fever, wounds, feeling tired, dental problems (see "Warnings and precautions").
- if your child has moderate or severe heart failure. It is important to tell your doctor if your child has had or has a serious heart condition (see "Warnings and precautions").

Warnings and precautions

Talk to your child's doctor or pharmacist before using Idacio

Allergic reaction

- If your child experiences allergic reactions with symptoms such as chest tightness, wheezing, dizziness, swelling or rash do not inject more Idacio and contact your doctor immediately since, in rare cases, these reactions can be life threatening.

Infection

- If your child has an infection, including long-term or localised infection (for example, leg ulcer) consult your doctor before starting Idacio. If you are unsure, contact your doctor.
- Your child might get infections more easily while receiving Idacio treatment. This risk may increase if his/her lung function is reduced. These infections may be more serious and include tuberculosis, infections caused by viruses, fungi, parasites or bacteria, or other unusual infectious organisms and sepsis (blood poisoning). In rare cases, these infections may be life-threatening. It is important to tell your doctor if your child gets symptoms such as fever, wounds, feeling tired or dental problems. Your doctor may recommend temporarily stopping Idacio.

Tuberculosis (TB)

- As cases of tuberculosis have been reported in patients treated with adalimumab, your doctor will check your child for signs and symptoms of tuberculosis before starting Idacio. This will include a thorough medical evaluation including your child's medical history and screening tests (for example chest X-ray and a tuberculin test). The conduct and results of these tests should be recorded on your child's patient reminder card. It is very important that you tell your doctor if your child has ever had tuberculosis, or if he/she has been in close contact with someone who has had tuberculosis. Tuberculosis can develop during therapy even if your child has had preventative treatment for tuberculosis. If symptoms of tuberculosis (persistent cough, weight loss, listlessness, mild fever), or any other infection appear during or after therapy tell your doctor immediately.

Travel/recurrent infection

- Tell your doctor if your child has lived or travelled in regions where fungal infections such as histoplasmosis, coccidioidomycosis or blastomycosis are common.
- Tell your doctor if your child has a history of recurrent infections or other conditions that increase the risk of infections.

Hepatitis B virus

- Tell your doctor if your child is a carrier of the hepatitis B virus (HBV), if he/she has active HBV infection or if you think he/she might be at risk of contracting HBV. Your child's doctor should test your child for HBV. Adalimumab can reactivate HBV infection in people who carry this virus. In some rare cases, especially if your child is taking other medicines that suppress the immune system, reactivation of HBV infection can be life-threatening.

Symptoms of infections

- It is important to tell your doctor if your child gets symptoms of infections, such as fever, wounds, feeling tired or dental problems.

Surgery or dental procedures

- If your child is about to have surgery or dental procedures tell your doctor that he/she is taking Idacio. Your doctor may recommend temporarily stopping Idacio.

Demyelinating disease

- If your child has or develops a demyelinating disease (a disease that affects the insulating layer around the nerves, such as multiple sclerosis), your doctor will decide if he/she should receive or continue to receive Idacio. Tell your doctor immediately if your child gets symptoms like changes in vision, weakness in arms or legs or numbness or tingling in any part of the body.

Vaccine

- Certain vaccines contain living but weakened forms of bacteria or disease-causing bacteria or viruses and should not be given during treatment with Idacio in case they cause infections. Check with your doctor before your child receives any vaccines. It is recommended that, if possible, children be given all the scheduled vaccinations for their age before they start treatment with Idacio. If you receive Idacio while you are pregnant, your baby may be at higher risk for getting an infection for up to about five months after the last dose you received during pregnancy. It is important that you tell your baby's doctors and other health care professionals about your Idacio use during your pregnancy so they can decide when your baby should receive any vaccine.

Heart failure

- It is important to tell your doctor if your child has had or has a serious heart condition. If your child has mild heart failure and is being treated with Idacio, his/her heart failure status must be closely monitored by your doctor. If he/she develops new or worsening symptoms of heart failure (e.g. shortness of breath, or swelling of his/her feet), you must contact your doctor immediately. Your doctor will decide if your child should receive Idacio.

Fever, bruising, bleeding or looking pale

- In some patients the body may fail to produce enough of the blood cells that help your child's body fight off infections or help him/her to stop bleeding. If your child develops a fever that does not go away, bruises or bleeds very easily or looks very pale, call your doctor right away. Your doctor may decide to stop treatment.

Cancer

- There have been very rare cases of certain kinds of cancer in children and adults taking adalimumab or other TNFα blockers. People with more serious rheumatoid arthritis who have had the disease for a long time may have a higher than average risk of getting lymphoma and leukaemia (cancers that affect blood cells and bone marrow). If your child takes Idacio the risk of getting lymphoma, leukaemia, or other cancers may increase. On rare occasions, a specific and severe type of lymphoma, has been observed in patients taking adalimumab. Some of those patients were also treated with the medicines azathioprine or mercaptopurine. Tell your doctor if your child is taking azathioprine or mercaptopurine with Idacio.
- In addition cases of non-melanoma skin cancer have been observed in patients taking adalimumab. If new areas of damaged skin appear during or after treatment or if existing marks or areas of damage change appearance, tell your doctor.
- There have been cases of cancers, other than lymphoma, in patients with a specific type of lung disease called chronic obstructive pulmonary disease (COPD) treated with another TNFα blocker. If your child has COPD, or is a heavy smoker, you should discuss with your doctor whether treatment with a TNFα blocker is appropriate for your child.
- On rare occasions, treatment with Idacio could result in lupus-like syndrome. Contact your doctor if symptoms such as persistent unexplained rash, fever, joint pain or tiredness occur.

Other medicines and Idacio

Tell your child's doctor or pharmacist if your child is taking, has recently taken or might take any other medicines.

Idacio can be taken together with methotrexate or certain disease-modifying anti-rheumatic agents (sulfasalazine, hydroxychloroquine, leflunomide and injectable gold preparations), corticosteroids or pain medications including non-steroidal anti-inflammatory drugs (NSAIDs).

Your child should not take Idacio with medicines containing the active substances anakinra or abatacept due to increased risk of serious infection. The combination of adalimumab as well as other TNF-antagonists and anakinra or abatacept is not recommended based upon the possible increased risk for infections, including serious infections and other potential pharmacological interactions. If you have questions, please ask your doctor.

Pregnancy and breast-feeding

If you think your child may be pregnant or is planning to have a baby, ask your doctor or pharmacist for advice before they use this medicine.

Your child is advised to avoid becoming pregnant and must use adequate contraception while using Idacio and for at least 5 months after the last Idacio injection. If your child becomes pregnant, you should see your child's doctor.

Idacio should only be used during a pregnancy if needed.

According to a pregnancy study, there was no higher risk of birth defects when the mother had received adalimumab during pregnancy compared with mothers with the same disease who did not receive adalimumab.

Idacio can be used during breast-feeding.

If your child received Idacio during her pregnancy, her baby may have a higher risk for getting an infection. It is important that you tell her baby's doctors and other health care professionals about her Idacio use during her pregnancy before the baby receives any vaccine (for more information see section on vaccination).

Driving and using machines

Idacio may have a minor influence on the ability to drive, cycle or use machines. Room spinning sensation (vertigo) and vision disturbances may occur after taking Idacio.

Idacio contains sodium

This medicine contains less than 1 mmol of sodium (23 mg) per 0.8 ml dose, that is to say essentially 'sodium-free'.

3. How to use Idacio

Always use this medicine exactly as your child's doctor or pharmacist has instructed. Check with your child's doctor or pharmacist if you are not sure about any of the instructions or if you have any questions. Your doctor may prescribe another strength of Idacio if your child needs a different dose.

Idacio is injected under the skin (subcutaneous use). A 40 mg pre-filled syringe and a 40 mg pre-filled pen are also available for use.

The recommended doses for Idacio in each of the approved uses are shown in the following table.

Polvarticular juvenile idiopathic arthritis			
Age or body weight	How much and how often to take?	Notes	
Children, adolescents and adults from 2 years of age weighing 30 kg or more	40 mg every other week	Not applicable	
Children and adolescents from 2 years of age weighing 10 kg to less than 30 kg	20 mg every other week	Not applicable	

Enthesitis-related arthritis			
Age or body weight	How much and how often to take?	Notes	
Children, adolescents and adults from 6 years of age weighing 30 kg or more	40 mg every other week	Not applicable	
Children and adolescents from 6 years of age weighing 15 kg to less than 30 kg	20 mg every other week	Not applicable	

Paediatric plaque psoriasis			
Age or body weight	How much and how often to take?	Notes	
Children and adolescents from 4 to 17 years of age weighing 30 kg or more	Initial dose of 40 mg, followed by 40 mg one week later. <p>Thereafter, the usual dose is 40 mg every other week.</p>	Not applicable	
Children and adolescents from 4 to 17 years of age weighing 15 kg to less than 30 kg	Initial dose of 20 mg, followed by 20 mg one week later. <p>Thereafter, the usual dose is 20 mg every other week.</p>	Not applicable	

Hidradenitis suppurativa			
Age or body weight	How much and how often to take?	Notes	
Adolescents from 12 to 17 years of age weighing 30 kg or more	Initial dose of 80 mg (as two 40 mg injections in one day), followed by 40 mg every other week starting one week later.	If this dose does not work well enough, your doctor may increase the dosage to 40 mg every other week or 80 mg every other week.	
		It is recommended that you use an antiseptic wash daily on the affected areas.	

Paediatric Crohn's disease			
Age or body weight	How much and how often to take?	Notes	
Children and adolescents from 6 to 17 years of age weighing 40 kg or more	Initial dose of 80 mg (as two 40 mg injections in one day), followed by 40 mg two weeks later. <p>If a faster response is required, your child's doctor may prescribe an initial dose of 160 mg (as four 40 mg injections in one day or as two 40 mg injections per day for two consecutive days) followed by 80 mg (as two 40 mg injections in one day) two weeks later.</p> <p>Thereafter, the usual dose is 40 mg every other week.</p>	If this dose does not work well enough, your child's doctor may increase the dosage to 40 mg every week or 80 mg every other week.	
Children and adolescents from 6 to 17 years of age weighing less than 40 kg	Initial dose of 40 mg, followed by 20 mg two weeks later. <p>If a faster response is required, your child's doctor may prescribe an initial dose of 80 mg (as two 40 mg injections in one day) followed by 40 mg two weeks later.</p> <p>Thereafter, the usual dose is 20 mg every other week.</p>	If this dose does not work well enough, your child's doctor may increase the dose frequency to 20 mg every week.	

Paediatric uveitis			
Age or body weight	How much and how often to take?	Notes	
Children and adolescents from 2 years of age weighing less than 30 kg	20 mg every other week	Your child's doctor may prescribe an initial dose of 40 mg which may be administered one week prior to the start of the usual dose. Idacio is recommended for use in combination with methotrexate.	
Children and adolescents from 2 years of age weighing 30 kg or more	40 mg every other week	Your child's doctor may prescribe an initial dose of 80 mg which may be administered one week prior to the start of the usual dose. Idacio is recommended for use in combination with methotrexate.	

Method and route of administration

Idacio is administered by injection under the skin (by subcutaneous injection).

Detailed instructions on how to inject Idacio are provided in section 7 'Instructions for use'.

If you use more Idacio than you should

If you accidentally inject a larger amount of Idacio liquid, or if you inject Idacio more frequently than told to by your doctor, call your doctor and tell him/her that your child has taken more. Always take the outer carton or the vial of the medicine with you, even if it is empty

If you use less Idacio than you should

If you accidentally inject a smaller amount of Idacio liquid, or if you inject Idacio less frequently than told to by your child's doctor or pharmacist, you should call your child's doctor or pharmacist and tell him/her that your child has taken less. Always take the outer carton or the vial of the medicine with you, even if it is empty.

If you forget to use Idacio

If you forget to give your child an Idacio injection, you should inject the Idacio dose as soon as you remember. Then administer your child's next dose as you would have on the originally scheduled day, had you not forgotten a dose.

If your child stops using Idacio

The decision to stop using Idacio should be discussed with your child's doctor. Your child's symptoms may return upon stopping treatment.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Most side effects are mild to moderate. However, some may be serious and require treatment. Side effects may occur up to 4 months or more after the last Idacio injection.

Seek medical attention urgently, if you notice any of the following signs of allergic reaction or heart failure:

- severe rash, hives;
- swollen face, hands, feet;
- trouble breathing, swallowing;
- shortness of breath with exertion or upon lying down or swelling of the feet.

Tell your doctor as soon as possible, if you notice any of the following:

- signs and symptoms of infection such as fever, feeling sick, wounds, dental problems, burning on urination, feeling weak or tired or coughing;
- symptoms of nerve problems such as tingling, numbness, double vision or arm or leg weakness;
- signs of skin cancer such as a bump or open sore that doesn't heal;
- signs and symptoms suggestive of blood disorders such as persistent fever, bruising, bleeding, paleness.

The following side effects have been observed with adalimumab:

- Very common** (may affect more than 1 in 10 people)
 - injection site reactions (including pain, swelling, redness or itching);
 - respiratory tract infections (including cold, runny nose, sinus infection, pneumonia);
 - headache;
 - abdominal (belly) pain;
 - nausea and vomiting;
 - rash;
 - pain in the muscles.

- Common** (may affect up to 1 in 10 people)
 - serious infections (including blood poisoning and influenza);
 - intestinal infections (including gastroenteritis);
 - skin infections (including cellulitis and shingles);
 - ear infections;
 - mouth infections (including tooth infections and cold sores);
 - reproductive tract infections;
 - urinary tract infection;
 - fungal infections;
 - joint infections;
 - benign tumours;
 - skin cancer;
 - allergic reactions (including seasonal allergy);
 - dehydration;
 - mood swings (including depression);
 - anxiety;
 - difficulty sleeping;
 - sensation disorders such as tingling, pricking or numbness;
 - migraine;
 - symptoms of nerve root compression (including low back pain and leg pain);
 - vision disturbances;
 - eye inflammation;
 - inflammation of the eye lid and eye swelling;
 - vertigo (sensation of room spinning);
 - sensation of heart beating rapidly;
 - high blood pressure;
 - flushing;
 - haematoma (a solid swelling with clotted blood);
 - cough;
 - asthma;
 - shortness of breath;
 - gastrointestinal bleeding;
 - dyspepsia (indigestion, bloating, heart burn);
 - acid reflux disease;
 - sicca syndrome (including dry eyes and dry mouth);
 - itching;
 - Itchy rash;
 - bruising;
 - inflammation of the skin (such as eczema);
 - breaking of finger nails and toe nails;
 - increased sweating;
 - hair loss;
 - new onset or worsening of psoriasis;
 - muscle spasms;
 - blood in urine;
 - kidney problems;
 - chest pain;
 - oedema (a build-up of fluid in the body which causes the affected tissue to swell);
 - fever;
 - reduction in blood platelets which increases risk of bleeding or bruising;
 - impaired healing.

Uncommon (may affect up to 1 in 100 people)

- unusual infections (which include tuberculosis and other infections) that occur when resistance to disease is lowered;
- neurological infections (including viral meningitis);
- eye infections;
- bacterial infections;
- diverticulitis (inflammation and infection of the large intestine);
- cancer, including cancer that affects the lymph system (lymphoma) and melanoma (a type of skin cancer);
- immune disorders that could affect the lungs, skin and lymph nodes (most commonly as a condition called sarcoidosis);
- vasculitis (inflammation of blood vessels);
- tremor;
- neuropathy (nerve damage);
- stroke;
- double vision;
- hearing loss, buzzing;
- sensation of heart beating irregularly such as skipped beats;
- heart problems that can cause shortness of breath or ankle swelling;
- heart attack;
- a sac in the wall of a major artery, inflammation and clot of a vein, blockage of a blood vessel;
- lung diseases causing shortness of breath (including inflammation);
- pulmonary embolism (blockage in an artery of the lung);
- pleural effusion (abnormal collection of fluid in the pleural space);
- inflammation of the pancreas which causes severe pain in the abdomen and back;
- difficulty in swallowing;
- facial oedema (swelling);
- gallbladder inflammation, gallbladder stones;
- fatty liver (build-up of fat in liver cells);
- night sweats;
- scar;
- abnormal muscle breakdown;
- systemic lupus erythematosus (an immune disorder including inflammation of skin, heart, lung, joints and other organ systems);
- sleep interruptions;
- impotence;
- inflammations.

Rare (may affect up to 1 in 1,000 people)

- leukemia (cancer affecting the blood and bone marrow);
- severe allergic reaction with shock;
- multiple sclerosis;
- nerve disorders (such as inflammation of the optic nerve to the eye, and Guillain-Barré syndrome, a condition that may cause muscle weakness, abnormal sensations, tingling in the arms and upper body);
- heart stops pumping;
- pulmonary fibrosis (scarring of the lung);
- intestinal perforation (hole in the wall of the gut);
- hepatitis (liver inflammation);
- reactivation of hepatitis B infection;
- autoimmune hepatitis (inflammation of the liver caused by the body's own immune system);
- cutaneous vasculitis (inflammation of blood vessels in the skin);
- Stevens-Johnson syndrome (life-threatening reaction with flu-like symptoms and blistering rash);
- facial oedema (swelling) associated with allergic reactions;
- erythema multiforme (inflammatory skin rash);
- lupus-like syndrome;
- angioedema (localized swelling of the skin);
- lichenoid skin reaction (itchy reddish-purple skin rash).

Not known (frequency cannot be estimated from available data)

- hepatosplenic T-cell lymphoma (a rare blood cancer that is often fatal);
- Merkel cell carcinoma (a type of skin cancer);
- liver failure;
- worsening of a condition called dermatomyositis (seen as a skin rash accompanying muscle weakness).

Some side effects observed with adalimumab may not have symptoms and may only be discovered through blood tests. These include:

Very common (may affect more than 1 in 10 people)

- low blood measurements for white blood cells;
- low blood measurements for red blood cells;
- increased lipids in the blood;
- raised liver enzymes.

Common (may affect up to 1 in 10 people)

- high blood measurements for white blood cells;
- low blood measurements for platelets;
- increased uric acid in the blood;
- abnormal blood measurements for sodium;
- low blood measurements for calcium;
- low blood measurements for phosphat;
- high blood sugar;
- high blood measurements for lactate dehydrogenase;
- autoantibodies present in the blood;
- low blood potassium.

Uncommon (may affect up to 1 in 100 people)

- raised bilirubin measurement (liver blood test).

Rare (may affect up to 1 in 1,000 people):

- low blood measurements for white blood cells, red blood cells and platelet count.

Reporting of side effects

If your child gets any side effects, talk to your child's doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the national reporting system listed below:

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland

HPRA Pharmacovigilance

Earlscort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

7. Instructions For Use

Idacio®

Single use pre-filled syringe (adalimumab) for subcutaneous injection
40 mg



Note: images for illustration purposes only.

Read carefully these entire instructions before using your Idacio pre-filled syringe.

Important Information

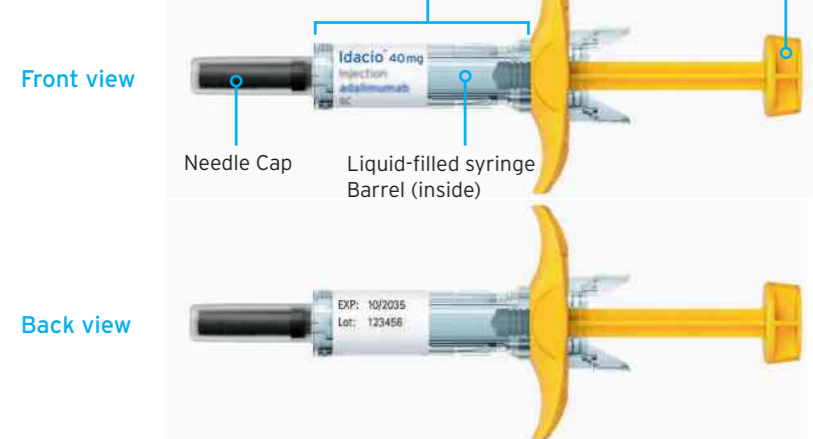
- Only use Idacio pre-filled syringe if your healthcare professional has trained you on how to use the pre-filled syringe correctly.
- Idacio is a pre-filled syringe for single use only.
- Idacio pre-filled syringe has a clear needle guard that covers the needle after the injection is complete.
- Children under 12 years of age are not allowed to inject themselves and injection must be done by a trained adult.
- Keep Idacio pre-filled syringe and the sharps disposal container out of reach and sight of children.
- Do not shake. Shaking can damage the pre-filled syringe and the medicine.
- Do not use Idacio the pre-filled syringe if liquid appears cloudy or discolored, or has particles or flakes in it. The liquid should be clear and colorless.
- Do not try to activate the clear needle guard before injecting.
- Do not insert your fingers into the opening of the clear needle guard.
- Do not use an Idacio pre-filled syringe that has been frozen or left in direct sunlight.
- Do not use the Idacio pre-filled syringe if it has been dropped or crushed, as the pre-filled syringe may be broken even if you cannot see the break. Use a new pre-filled syringe instead.

Storage Information

- Store the pre-filled syringe in its original box to protect it from light.
- Store the pre-filled syringe in a refrigerator between 2°C to 8°C.
- If needed, for example when traveling, a single pre-filled syringe can be stored at room temperature for up to 14 days.

Get Familiar with your Idacio Pre-Filled Syringe

Before Use



After Use

Step 1 Prepare for your Injection

Each box of Idacio pre-filled syringe comes with two or six syringes.

- 1.1 Prepare a clean flat surface, such as a table or countertop, in a well-lit area.
- 1.2 You will also need (Figure A):
 - an alcohol pad (included in the box)
 - a cotton ball or gauze, and
 - a sharps disposal container.

Open your sharps disposal container so it is ready to use.



Figure A



N0910202B

- 1.3 Remove the box from the refrigerator (Figure B).



Figure B

- 1.4 Check the expiration date on the side of the box (Figure B).

Warning: Do not use if expiration date has passed.

- 1.5 **Caution:** Do not pick up the syringe by the plunger or the needle cap. Doing so could damage the syringe or activate the clear needle guard. Take a syringe out of the original box:

- place two fingers on middle of the clear needle guard
- pull the syringe straight up and out of the packaging (Figure C).

Put it on a clean flat surface.

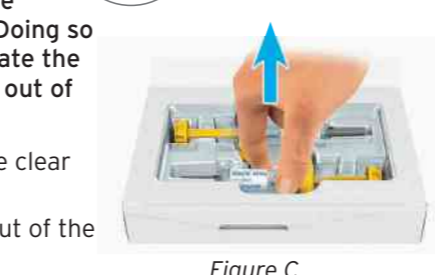


Figure C

- 1.6 Place the remaining syringe(s) in its (their) original box back in the refrigerator (Figure D).

Refer to Storage information for how to store your unused syringe.

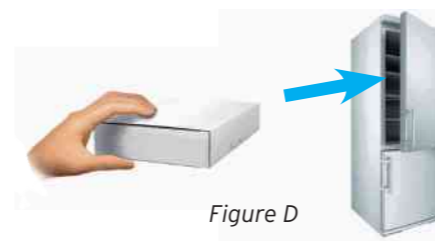


Figure D

- 1.7 Leave the syringe at room temperature for 30 minutes to allow the medicine to warm up. Injecting cold medicine can be painful (Figure E).

Warning: Do not warm the syringe any other way, such as in a microwave, hot water, or direct sunlight.

Warning: Do not remove the needle cap while allowing syringe to reach room temperature.



Figure E

Step 2 Wash your Hands

- 2.1 Wash your hands well with soap and water (Figure F) and dry them.

Warning: Gloves will not replace the need for washing hands.

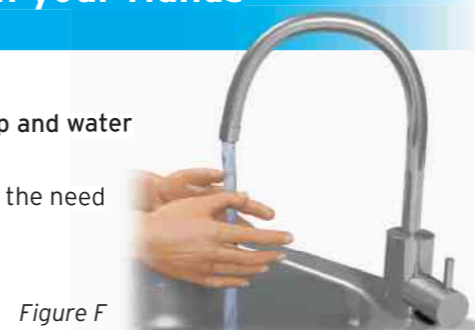


Figure F

Step 3 Check the Syringe

- 3.1 Check the syringe to make sure that:

- The syringe, the clear needle guard, and the needle cap are not cracked or damaged (Figure G).
- The needle cap is securely attached (Figure H).
- The needle guard spring is not extended (Figure I).

Warning: Do not use the syringe if it shows any sign of damage.

If so, throw away the syringe in a sharps disposal container and contact your healthcare professional or pharmacist.

- 3.2 Check the liquid to make sure that:

- The liquid is clear, colorless, and free of particles (Figure J).

Warning: Do not use the syringe if liquid contains particles, or is cloudy or if it is colored or has flakes in it.



Figure G



Figure H

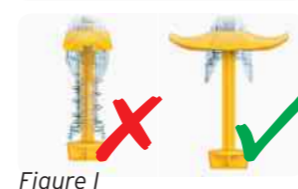


Figure I

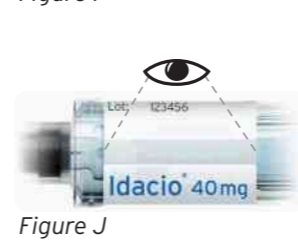


Figure J

- 3.3 Check the label to make sure that:

- The name on the syringe says Idacio (Figure K).
- The expiration date on syringe has not passed (Figure K).

Warning: Do not use the syringe if:

- The name on the syringe is not Idacio.
- The expiration date on the syringe has passed.

If so, throw away the syringe in a sharps disposal container and contact your healthcare professional or pharmacist.

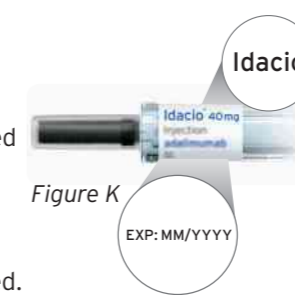


Figure K

Step 4 Choose the Injection Site

- 4.1 Choose an injection site (Figure L) on:

- Top of the thighs.
- Abdomen (inject at least 5 centimeters away from the belly button).



Figure L

- 4.2 Choose a different site (at least 2.5 centimeters away from the previous injection site) each time to reduce redness, irritation or other skin problems.

Warning: Do not inject into an area that is sore (tender), bruised, red, hard, scarred or where you have stretch marks.

Warning: If you have psoriasis, do not inject into any lesions or red, thick, raised or scaly patches.

Step 5 Clean the Injection Site

- 5.1 Wipe the skin of your injection site with an alcohol pad to clean it. (Figure M)

Warning: Do not blow on or touch the injection site after cleaning.



Figure M

Step 6 Give your Injection

- 6.1 Remove the needle cap

- Always hold the syringe by the clear needle guard.
- Hold the syringe upward and pull the needle cap straight off (Figure N).

You may see drops of liquid at the needle tip.

- Throw away the needle cap.
- **Warning:** Do not touch the needle.



Figure N

- 6.2 Pinch the skin

- Hold the syringe like a pencil.
- With your other hand gently pinch skin (without squeezing) to avoid injecting into a muscle (Figure O).



Figure O

- 6.3 Insert the needle

- With a quick, short motion, push the needle all the way into the skin at an angle between 45° and 90° (Figure P).
- After the needle is inserted, release the pinched skin.

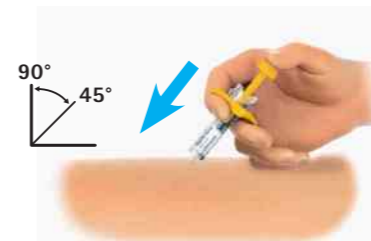


Figure P

- 6.4 Inject

- Use your thumb to gently push plunger all the way down (Figure Q).



Figure Q

- Give plunger a final push to ensure the full dose has been injected (Figure R).

- Hold the syringe firmly without moving it, at the same angle (Figure R).

Do not remove the needle from the skin when the plunger reaches the end.



Figure R

- Slowly release your thumb up. This will allow the needle to move up into the clear needle guard and cover the entire needle (Figure S).

Warning: Call your healthcare professional or pharmacist if:

- You did not inject the full dose or
- The clear needle guard does not activate after injecting.

Warning: Do not reuse a syringe in case of partial injection.

Do not try to recap needle as it could lead to needle stick injury.



Figure S

- 6.5 If there is blood or liquid on the injection site, gently press a cotton ball or gauze on the skin (Figure T).



Figure T

Step 7 Throw away your Syringe

- 7.1 Throw away your used syringe in a sharps disposal container right away after use (Figure U).

Warning: Keep your sharps disposal container out of the reach of children.

Warning: Do not throw away the syringe in your household trash.

If you do not have a sharps disposal container, you may use a household container that is:

- Made of a heavy-duty plastic;
- Can be closed with a tight-fitting, puncture-resistant lid; that will keep sharps from coming out,
- Upright and stable during use,
- Leak-resistant and
- Properly labeled to warn of hazardous waste inside the container.



Figure U

- 7.2 When your sharps disposal container is almost full, you will need to follow your local guidelines for the right way to dispose of your sharps disposal container.

Do not recycle your used sharps disposal container.

Step 8 Record your Injection

- 8.1 To help you remember when and where to do your next injection, you should keep a record of the dates and injection sites used for your injections (Figure V).



Figure V

Information for the patient

Idacio® FRESENIUS KABI

40 mg solution for injection in pre-filled syringe adalimumab

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Your doctor will also give you a patient reminder card, which contains important safety information that you need to be aware of before you are given Idacio and during treatment with Idacio. Keep this patient reminder card with you during your treatment and for 4 months after your (or your child's) last injection of Idacio.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet (see section 4).

What is in this leaflet

- What Idacio is and what it is used for
- What you need to know before you use Idacio
- How to use Idacio
- Possible side effects
- How to store Idacio
- Contents of the pack and other information
- Instructions for use

1. What Idacio is and what it is used for

Idacio contains the active substance adalimumab, a medicine that acts on your body's immune (defence) system.

Idacio is intended for the treatment of the following inflammatory diseases:

- rheumatoid arthritis,
- polyarticular juvenile idiopathic arthritis,
- enthesitis-related arthritis,
- ankylosing spondylitis,
- axial spondyloarthritis without radiographic evidence of ankylosing spondylitis,
- psoriatic arthritis,
- psoriasis,
- hidradenitis suppurativa,
- Crohn's disease,
- ulcerative colitis and
- non-infectious uveitis

The active ingredient in Idacio, adalimumab, is a monoclonal antibody. Monoclonal antibodies are proteins that attach to a specific target in the body.

The target of adalimumab is another protein called tumour necrosis factor (TNFα), which is present at increased levels in the inflammatory diseases listed above. By attaching to TNFα, Idacio blocks its action and reduces the inflammation in these diseases.

Rheumatoid arthritis

Rheumatoid arthritis is an inflammatory disease of the joints.

Idacio is used to treat rheumatoid arthritis in adults. If you have moderate to severe active rheumatoid arthritis, you may first be given other disease-modifying medicines, such as methotrexate. If these medicines do not work well enough, you will be given Idacio to treat your rheumatoid arthritis.

Idacio can also be used to treat severe, active and progressive rheumatoid arthritis without previous methotrexate treatment.

Idacio can slow down the damage to the cartilage and bone of the joints caused by the disease and improve physical function.

Usually, Idacio is used with methotrexate. If your doctor considers that methotrexate is inappropriate, Idacio can be given alone.

Polyarticular juvenile idiopathic arthritis and enthesitis-related arthritis

Polyarticular juvenile idiopathic arthritis and enthesitis-related arthritis are inflammatory diseases of the joints that usually first appear in childhood.

Idacio is used to treat polyarticular juvenile idiopathic arthritis in children and adolescents aged 2 to 17 years and enthesitis-related arthritis in children and adolescents aged 6 to 17 years. Patients may first be given other disease-modifying medicines, such as methotrexate. If these medicines do not work well enough, patients will be given Idacio to treat their polyarticular juvenile idiopathic arthritis or enthesitis-related arthritis.

Ankylosing spondylitis and axial spondyloarthritis without radiographic evidence of ankylosing spondylitis

Ankylosing spondylitis and axial spondyloarthritis without radiographic evidence of ankylosing spondylitis, are inflammatory diseases of the spine.

Idacio is used in adults to treat these conditions. If you have ankylosing spondylitis or axial spondyloarthritis without radiographic evidence of ankylosing spondylitis, you will first be given other medicines. If these medicines do not work well enough, you will be given Idacio to reduce the signs and symptoms of your disease.

Psoriatic arthritis

Psoriatic arthritis is an inflammatory disease of the joints associated with psoriasis.

Idacio is used to treat psoriatic arthritis in adults. Idacio can slow down the damage to the cartilage and bone of the joints caused by the disease and improve physical function.

Plaque psoriasis in adults and children

Plaque psoriasis is an inflammatory skin condition that causes red, flaky, crusty patches of skin covered with silvery scales. Plaque psoriasis can also affect the nails, causing them to crumble, become thickened and lift away from the nail bed which can be painful. Psoriasis is believed to be caused by a problem with the body's immune system that leads to an increased production of skin cells.

Idacio is used to treat moderate to severe plaque psoriasis in adults. Idacio is also used to treat severe plaque psoriasis in children and adolescents adolescents aged 4 to 17 years for whom medicines applied to the skin and treatment with UV light have either not worked very well or are not suitable.

Hidradenitis suppurativa in adults and adolescents

Hidradenitis suppurativa (sometimes called acne inversa) is a long-term and often painful inflammatory skin disease. Symptoms may include tender nodules (lumps) and abscesses (boils) that may leak pus. It most commonly affects specific areas of the skin, such as under the breasts, the armpits, inner thighs, groin and buttocks. Scarring may also occur in affected areas.

Idacio is used to treat hidradenitis suppurativa in adults and adolescents from 12 years of age. Idacio can reduce the number of nodules and abscesses you have, and the pain that is often associated with the disease. You may first be given other medicines. If these medicines do not work well enough, you will be given Idacio.

Crohn's disease in adults and children

Crohn's disease is an inflammatory disease of the gut.

Idacio is used to treat Crohn's disease in adults and children aged 6 to 17 years. If you have Crohn's disease you will first be given other medicines. If you do not respond well enough to these medicines, you will be given Idacio to reduce the signs and symptoms of your Crohn's disease.

Ulcerative colitis

Ulcerative colitis is an inflammatory disease of the bowel.

Idacio is used to treat ulcerative colitis in adults. If you have ulcerative colitis you will first be given other medicines. If these medicines do not work well enough, you will be given Idacio to reduce the signs and symptoms of your disease.

Non-infectious uveitis in adults and children

Non-infectious uveitis is an inflammatory disease affecting certain parts of the eye. The inflammation leads to a decrease of vision and/or the presence of floaters in the eye (black dots or wispy lines that move across the field of vision). Idacio works by reducing this inflammation.

Idacio is used to treat:

- adults with non-infectious uveitis with inflammation affecting the back of the eye
- children from 2 years of age with chronic non-infectious uveitis with inflammation affecting the front of the eye.

2.What you need to know before you use Idacio

Do not use Idacio

- if you are allergic to adalimumab or any of the other ingredients of this medicine (listed in section 6).
- if you have a severe infection, including tuberculosis, sepsis (blood poisoning) or other opportunistic infections (unusual infections associated with a weakened immune system). It is important that you tell your doctor if you have symptoms of infections, e.g. fever, wounds, feeling tired, dental problems (see “Warnings and precautions”).
- if you have moderate or severe heart failure. It is important to tell your doctor if you have had or have a serious heart condition (see “Warnings and precautions”).

Warnings and precautions

Talk to your doctor or pharmacist before using Idacio

Allergic reaction

- If you have allergic reactions with symptoms such as chest tightness, wheezing, dizziness, swelling or rash do not inject more Idacio and contact your doctor immediately since, in rare cases, these reactions can be life threatening.

Infection

- If you have an infection, including long-term or localised infection (for example, leg ulcer) consult your doctor before starting Idacio. If you are unsure, contact your doctor.
- You might get infections more easily while you are receiving Idacio treatment. This risk may increase if your white function is reduced. These infections may be more serious and include tuberculosis, infections caused by viruses, fungi, parasites or bacteria, or other unusual infectious organisms and sepsis (blood poisoning). In rare cases, these infections may be life-threatening. It is important to tell your doctor if you get symptoms such as fever, wounds, feeling tired or dental problems. Your doctor may recommend temporarily stopping Idacio.

Tuberculosis (TB)

- As cases of tuberculosis have been reported in patients treated with adalimumab, your doctor will check you for signs and symptoms of tuberculosis before starting Idacio. This will include a thorough medical evaluation including your medical history and screening tests (for example chest X-ray and a tuberculin test). The conduct and results of these tests should be recorded on your patient reminder card. It is very important that you tell your doctor if you have ever had tuberculosis, or if you have been in close contact with someone who has had tuberculosis. Tuberculosis can develop during therapy even if you have had preventative treatment for tuberculosis. If symptoms of tuberculosis (persistent cough, weight loss, listlessness, mild fever), or any other infection appear during or after therapy tell your doctor immediately.

Travel/recurrent infection

- Tell your doctor if you have lived or travelled in regions where fungal infections such as histoplasmosis, coccidioidomycosis or blastomycosis are common.
- Tell your doctor if you have a history of recurrent infections or other conditions that increase the risk of infections.

Hepatitis B virus

- Tell your doctor if you are a carrier of the hepatitis B virus (HBV), if you have active HBV infection or if you think you might be at risk of contracting HBV. Your doctor should test you for HBV. Adalimumab can reactivate HBV infection in people who carry this virus. In some rare cases, especially if you are taking other medicines that suppress the immune system, reactivation of HBV infection can be life-threatening.

Age over 65 years

- If you are over 65 years you may be more susceptible to infections while taking Idacio. You and your doctor should pay special attention to signs of infection while you are being treated with Idacio. It is important to tell your doctor if you get symptoms of infections, such as fever, wounds, feeling tired or dental problems.

Surgery or dental procedures

- If you are about to have surgery or dental procedures tell your doctor that you are taking Idacio. Your doctor may recommend temporarily stopping Idacio.

Demyelinating disease

- If you have or develop demyelinating disease (a disease that affects the insulating layer around the nerves, such as multiple sclerosis), your doctor will decide if you should receive or continue to receive Idacio. Tell your doctor immediately if you get symptoms like changes in your vision, weakness in your arms or legs or numbness or tingling in any part of your body.

Vaccine

- Certain vaccines contain living but weakened forms of disease-causing bacteria or viruses and should not be given during treatment with Idacio in case they cause infections. Check with your doctor before you receive any vaccines. It is recommended that, if possible, children be given all the scheduled vaccinations for their age before they start treatment with Idacio. If you receive Idacio while you are pregnant, your baby may be at higher risk for getting an infection for up to about five months after the last dose you received during pregnancy. It is important that you tell your baby's doctors and other health care professionals about your Idacio use during your pregnancy so they can decide when your baby should receive any vaccine.

Heart failure

- It is important to tell your doctor if you have had or have a serious heart condition. If you have mild heart failure and you are being treated with Idacio, your heart failure status must be closely monitored by your doctor. If you develop new or worsening symptoms of heart failure (e.g. shortness of breath, or swelling of your feet), you must contact your doctor immediately.

Fever, bruising, bleeding or looking pale

- In some patients the body may fail to produce enough of the blood cells that fight off infections or help you to stop bleeding. If you develop a fever that does not go away, or you bruise or bleed very easily or look very pale, call your doctor right away. Your doctor may decide to stop treatment.

Cancer

- There have been very rare cases of certain kinds of cancer in children and adults taking adalimumab or other TNFα blockers. People with more serious rheumatoid arthritis who have had the disease for a long time may have a higher than average risk of getting lymphoma and leukaemia (cancers that affect blood cells and bone marrow). If you take Idacio the risk of getting lymphoma, leukaemia, or other cancers may increase. On rare occasions, a

specific and severe type of lymphoma, has been observed in patients taking adalimumab. Some of those patients were also treated with the medicines azathioprine or mercaptopurine. Tell your doctor if you are taking azathioprine or mercaptopurine with Idacio.

- In addition cases of non-melanoma skin cancer have been observed in patients taking adalimumab. If new areas of damaged skin appear during or after treatment or if existing marks or areas of damage change appearance, tell your doctor.
- There have been cases of cancers, other than lymphoma, in patients with a specific type of lung disease called chronic obstructive pulmonary disease (COPD) treated with another TNFα blocker. If you have COPD, or are a heavy smoker, you should discuss with your doctor whether treatment with a TNFα blocker is appropriate for you.
- On rare occasions, treatment with Idacio could result in lupus-like syndrome. Contact your doctor if symptoms such as persistent unexplained rash, fever, joint pain or tiredness occur.

Children and adolescents

- Vaccinations: if possible children should be up to date with all vaccinations before using Idacio.
- Do not give Idacio to children with polyarticular juvenile idiopathic arthritis below the age of 2 years.
- Do not use the 40 mg pre-filled syringe or 40 mg pre-filled pen if doses other than 40 mg are recommended.

Other medicines and Idacio

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Idacio can be taken together with methotrexate or certain disease-modifying anti-rheumatic agents (sulfasalazine, hydroxychloroquine, leflunomide and injectable gold preparations), corticosteroids or pain medications including non-steroidal anti-inflammatory drugs (NSAIDs).

You should not take Idacio with medicines containing the active substances anakinra or abatacept due to increased risk of serious infection. The combination of adalimumab as well as other TNF-antagonists and anakinra or abatacept is not recommended based upon the possible increased risk for infections, including serious infections and other potential pharmacological interactions. If you have questions, please ask your doctor.

Pregnancy and breast-feeding

If you think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You are advised to avoid becoming pregnant and must use adequate contraception while using Idacio and for at least 5 months after the last Idacio injection. If you become pregnant, you should see your doctor.

Idacio should only be used during a pregnancy if needed.

According to a pregnancy study, there was no higher risk of birth defects when the mother had received adalimumab during pregnancy compared with mothers with the same disease who did not receive adalimumab.

Idacio can be used during breast-feeding.

If you receive Idacio during your pregnancy, your baby may have a higher risk for getting an infection. It is important that you tell your baby's doctors and other health care professionals about your Idacio use during your pregnancy before the baby receives any vaccine (for more information see section on vaccination).

Driving and using machines

Idacio may have a minor influence on your ability to drive, cycle or use machines. Room spinning sensation (vertigo) and vision disturbances may occur after taking Idacio.

Idacio contains sodium

This medicine contains less than 1 mmol of sodium (23 mg) per 0.8 ml dose, that is to say essentially 'sodium-free'.

3.How to use Idacio

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Idacio is injected under the skin (subcutaneous use). Patients requiring a dose less than 40 mg should use the 40 mg vial presentation of Idacio.

The recommended doses for Idacio in each of the approved uses are shown in the following table.

Rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis or axial spondyloarthritis without radiographic evidence of ankylosing spondylitis		
Age or body weight	How much and how often to take?	Notes
Adults	40 mg every other week	In rheumatoid arthritis, methotrexate is continued while using Idacio. If your doctor decides that methotrexate is inappropriate, Idacio can be given alone. <p>If you have rheumatoid arthritis and you do not receive methotrexate with your Idacio therapy, your doctor may decide to give Idacio 40 mg every week or 80 mg every other week.</p>
Polyarticular juvenile idiopathic arthritis		
Age or body weight	How much and how often to take?	Notes
Children, adolescents and adults from 2 years of age weighing 30 kg or more	40 mg every other week	Not applicable
Children and adolescents from 2 years of age weighing 10 kg to less than 30 kg	20 mg every other week	Not applicable

Enthesitis-related arthritis		
Age or body weight	How much and how often to take?	Notes
Children, adolescents and adults from 6 years of age weighing 30 kg or more	40 mg every other week	Not applicable
Children and adolescents from 6 years of age weighing 15 kg to less than 30 kg	20 mg every other week	Not applicable
Plaque psoriasis		
Age or body weight	How much and how often to take?	Notes
Adults	Initial dose of 80 mg (as two 40 mg injections in one day), followed by 40 mg given every other week starting one week after the initial dose. <p>You should continue to inject Idacio for as long as your doctor has told you.</p>	If this dose does not work well enough, your doctor may increase the dosage to 40 mg every week or 80 mg every other week.
Children and adolescents from 4 to 17 years of age weighing 30 kg or more	Initial dose of 40 mg, followed by 40 mg one week later. <p>Thereafter, the usual dose is 40 mg every other week.</p>	Not applicable

Adolescents from 12 to 17 years of age weighing 30 kg or more	Initial dose of 80 mg (as two 40 mg injections in one day), followed by 40 mg every other week starting one week after the initial dose.	If this dose does not work well enough, your doctor may increase the dosage to 40 mg every week or 80 mg every other week.
Children and adolescents from 6 to 17 years of age weighing less than 40 kg or more	Initial dose of 160 mg (as four 40 mg injections in one day or as two 40 mg injections per day for two consecutive days), followed by 80 mg (as two 40 mg injections in one day) two weeks later.	If this dose does not work well enough, your doctor may increase the dose frequency to 40 mg every week or 80 mg every other week.
Children, adolescents and adults from 6 years of age weighing 40 kg or more	Initial dose of 80 mg (as two 40 mg injections in one day), followed by 40 mg two weeks later.	If this dose does not work well enough, your doctor may increase the dose frequency to 40 mg every week or 80 mg every other week.
Children and adolescents from 6 to 17 years of age weighing less than 40 kg or more	Initial dose of 160 mg (as four 40 mg injections in one day or as two 40 mg injections per day for two consecutive days) followed by 80 mg (as two 40 mg injections in one day) two weeks later.	If this dose does not work well enough, your doctor may increase the dose frequency to 40 mg every week or 80 mg every other week.

Children and adolescents from 4 to 17 years of age weighing 15 kg to less than 30 kg	Initial dose of 20 mg, followed by 20 mg one week later.	Not applicable
	Thereafter, the usual dose is 20 mg every other week.	

Hidradenitis suppurativa		
Age or body weight	How much and how often to take?	Notes
Adults	Initial dose of 160 mg (as four 40 mg injections in one day or two 40 mg injections per day for two consecutive days), followed by an 80 mg dose (as two 40 mg injections on the same day) two weeks later. After two further weeks, continue with a dose of 40 mg every week or 80 mg every other week, as prescribed by your doctor.	It is recommended that you use an antiseptic wash daily on the affected areas.
Adolescents from 12 to 17 years of age weighing 30 kg or more	Initial dose of 80 mg (as two 40 mg injections in one day), followed by 40 mg every other week starting one week later.	If this dose does not work well enough, your doctor may increase the dose frequency to 40 mg every week or 80 mg every other week. <p>It is recommended that you use an antiseptic wash daily on the affected areas.</p>

Crohn's disease		
Age or body weight	How much and how often to take?	Notes
Children, adolescents and adults from 6 years of age weighing 40 kg or more	Initial dose of 80 mg (as two 40 mg injections in one day), followed by 40 mg two weeks later. <p>If a faster response is required, your doctor may prescribe an initial dose of 160 mg (as four 40 mg injections in one day or two 40 mg injections per day for two consecutive days) followed by 80 mg (as two 40 mg injections in one day) two weeks later.</p> <p>Thereafter, the usual dose is 40 mg every other week.</p>	If this dose does not work well enough, your doctor may increase the dose frequency to 40 mg every week or 80 mg every other week.
Children and adolescents from 6 to 17 years of age weighing less than 40 kg	Initial dose of 40 mg, followed by 20 mg two weeks later. <p>If a faster response is required, your doctor may prescribe a first dose of 80 mg (two 40 mg injections in one day), followed by 40 mg two weeks later.</p> <p>Thereafter, the usual dose is 20 mg every other week.</p>	If this dose does not work well enough, your doctor may increase the dose frequency to 20 mg every week.

Ulcerative colitis		
Age or body weight	How much and how often to take?	Notes
Adults	Initial dose of 160 mg (as four 40 mg injections in one day or as two 40 mg injections per day for two consecutive days), followed by 80 mg (as two 40 mg injections in one day) two weeks later. <p>Thereafter, the usual dose is 40 mg every other week.</p>	If this dose does not work well enough, your doctor may increase the dosage to 40 mg every other week or 80 mg every other week.

Non-infectious uveitis		
Age or body weight	How much and how often to take?	Notes
Adults	Initial dose of 80 mg (as two 40 mg injections), followed by 40 mg every other week starting one week after the initial dose. <p>You should continue to inject Idacio for as long as your doctor has told you.</p>	Corticosteroids or other medicines that influence the immune system may be continued while using Idacio. Idacio can also be given alone.
Children and adolescents from 2 years of age weighing less than 30 kg	20 mg every other week	Your doctor may prescribe an initial dose of 40 mg which may be administered one week prior to the start of the usual dose.
Children and adolescents from 2 years of age weighing at least 30 kg	40 mg every other week	Your doctor may also prescribe an initial dose of 80 mg which may be administered one week prior to the start of the usual dose.
		Idacio is recommended for use in combination with methotrexate.
		Idacio is recommended for use in combination with methotrexate.

Method and route of administration

Idacio is administered by injection under the skin (by subcutaneous injection).

Detailed instructions on how to inject Idacio are provided in section 7 'Instructions for use'.

If you use more Idacio than you should

If you accidentally inject Idacio more frequently than you should, call your doctor or pharmacist and explain that you have taken more than required. Always take the outer carton of the medicine with you, even if it is empty.

If you forget to use Idacio

If you forget to give yourself an injection, you should inject the next dose of Idacio as soon as you remember. Then take your next dose as you would have on your originally scheduled day, had you not forgotten a dose.

If you stop using Idacio

The decision to stop using Idacio should be discussed with your doctor. Your symptoms may return upon stopping treatment.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4.Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Most side effects are mild to moderate. However, some may be serious and require treatment. Side effects may occur up to 4 months or more after the last Idacio injection.

Very common (may affect more than 1 in 10 people)

- allergic reaction or heart failure:
- severe rash, hives;
- swollen face, hands, feet;
- trouble breathing, swallowing;
- shortness of breath with exertion or upon lying down or swelling of the feet.

Tell your doctor as soon as possible, if you notice any of the following:

- signs and symptoms of infection such as fever, feeling sick, wounds, dental problems, burning on urination, feeling weak or tired or coughing;
- symptoms of nerve problems such as tingling, numbness, double vision or arm or leg weakness;
- signs of skin cancer such as a bump or open sore that doesn't heal;
- signs and symptoms suggestive of blood disorders such as persistent fever, bruising, bleeding, paleness.

The following side effects have been observed with adalimumab:

Very common (may affect more than 1 in 10 people)

- injection site reactions (including pain, swelling, redness or itching);
- respiratory tract infections (including cold, runny nose, sinus infection, pneumonia);
- headache;
- abdominal (belly) pain;
- nausea and vomiting;
- rash;
- pain in the muscles.

Common (may affect up to 1 in 10 people)

- serious infections (including blood poisoning and influenza);
- intestinal infections (including gastroenteritis);
- skin infections (including cellulitis and shingles);
- ear infections;
- mouth infections (including tooth infections and cold sores);
- reproductive tract infections;
- urinary tract infection;
- fungal infections;
- joint infections;
- benign tumours;
- skin cancer;
- allergic reactions (including seasonal allergy);
- dehydration;
- mood swings (including depression);
- anxiety;
- difficulty sleeping;
- sensation disorders such as tingling, prickling or numbness;
- migraine;
- symptoms of nerve root compression (including low back pain and leg pain);
- vision disturbances;
- eye inflammation;
- inflammation of the eye lid and eye swelling;
- vertigo (sensation of room spinning);
- sensation of heart beating rapidly;
- high blood pressure;
- flushing;
- haematoma (a solid swelling with clotted blood);
- cough;
- asthma;
- shortness of breath;
- gastrointestinal bleeding;
- dyspepsia (indigestion, bloating, heart burn);
- acid reflux disease;
- sicca syndrome (including dry eyes and dry mouth);
- itching;
- itchy rash;
- bruising;
- inflammation of the skin (such as eczema);
- breaking of finger nails and toe nails;
- increased sweating;
- hair loss;
- new onset or worsening of psoriasis;
- muscle spasms;
- blood in urine;
- kidney problems;
- chest pain;
- oedema (a

7. Instructions For Use

Idacio®

Single use pre-filled pen (adalimumab) for subcutaneous injection 40mg



Note: images for illustration purposes only.

Read carefully these entire instructions before using your Idacio pre-filled pen.

Important Information

- Only use Idacio pre-filled pen if your healthcare professional has trained you how to use it correctly.
- The Idacio pre-filled pen comes as a ready to use single use pre-filled pen to give a full dose of adalimumab.
- Always inject using the technique your healthcare professional taught you.
- Children under 12 years of age are not allowed to inject themselves and injection must be done by a trained adult.
- Keep the Idacio pre-filled pen out of the reach of children.
- **Do not** insert your fingers into the opening of the safety guard.
- **Do not** use an Idacio pre-filled pen that has been frozen or left in direct sunlight.
- Talk to your healthcare professional if you have any questions or concerns.

Storage Information

- Store the pre-filled pen in its original box to protect it from light.
- Store the pre-filled pen in a refrigerator between 2°C to 8°C.
- If needed, for example when traveling, a single pre-filled pen can be stored at room temperature for up to 14 days.

Get Familiar with your Idacio Pre-filled pen

Before Use



After Use



Step 1 Prepare for your Injection

Each box of Idacio pre-filled pen comes with two or six pre-filled pens.

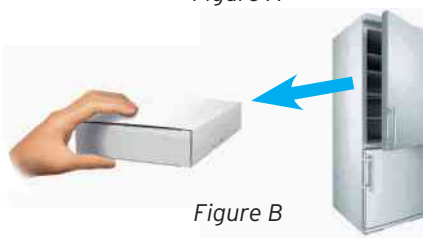
1.1 Prepare a clean flat surface, such as a table or countertop, in a well-lit area.

1.2 You will also need (Figure A):

- an alcohol pad (included in the box)
- a cotton ball or gauze, and
- a sharps disposal container.

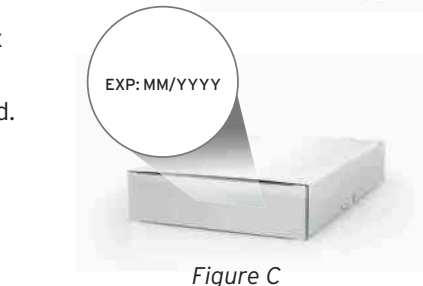


1.3 Remove the box from the refrigerator (Figure B).



1.4 Check the expiration date on the side of the box (Figure C).

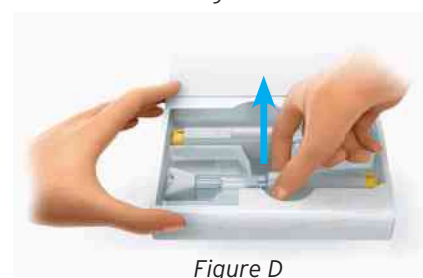
Warning: Do not use if expiration date has passed.



1.5 Take a pre-filled pen out of the original box:

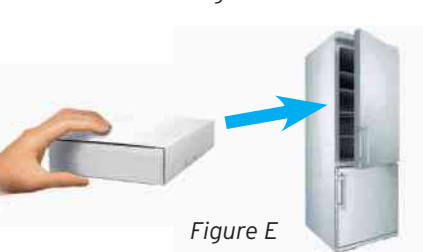
- place two fingers on the label area
- pull the pre-filled pen straight up and out of the packaging (Figure D).

Put it on a clean flat surface.



1.6 Place the remaining pre-filled pen(s) in its original box back in the refrigerator (Figure E).

Refer to Storage Information for how to store your unused pre-filled pen.



1.7 Leave the pre-filled pen at room temperature for at least 30 minutes to allow the medicine to warm up (Figure F).

Injecting cold medicine may be painful.

Warning: Do not warm the pre-filled pen any other way, such as in a microwave, hot water, or direct sunlight.

Warning: Do not remove the needle cap until you are ready to inject.



Figure F



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Step 2 Wash your Hands

2.8 Wash your hands with soap and water (Figure G) and dry them well.

Warning: Gloves **do not** replace the need for washing hands.

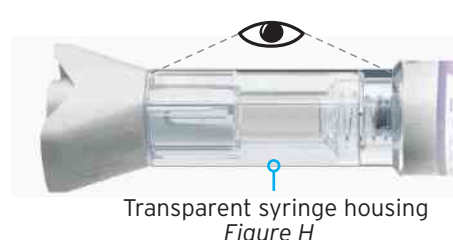


Figure G

Step 3 Check the Pre-filled Pen

3.1 Check the transparent syringe housing to make sure that:

- The liquid is clear, colorless, and free of particles (Figure H).
- The glass syringe is not cracked or broken (Figure H).



Transparent syringe housing
Figure H

Warning: Do not use the pre-filled pen if the liquid contains particles, or is cloudy or if it is colored, or has flakes in it or shows any sign of damage.

If so, throw it away in a sharps disposal container and contact your healthcare professional or pharmacist.

3.2 Check the label to make sure that:

- The name on the pre-filled pen says Idacio (Figure I).
- The expiration date on the pre-filled pen has not passed (Figure I).

Warning: Do not use the pre-filled pen if the name on the label is not Idacio and/or the expiration date on the label has passed.

If so, throw away the pre-filled pen in a sharps disposal container and contact your healthcare professional or pharmacist.



Figure I

Step 4 Choose the Injection Site

4.1 Choose an injection site (Figure J) on:

- Top of the thighs.
- Abdomen (inject at least 5 centimeters away from the belly button).



Figure J

4.2 Choose a different site (at least 2.5 centimeters away from the previous injection site) each time to reduce redness, irritation or other skin problems.

Warning: Do not inject into an area that is sore (tender), bruised, red, hard, scarred or where you have stretch marks.

Warning: If you have psoriasis, **do not** inject into any lesions or red, thick, raised or scaly patches.

Step 5 Clean the Injection Site

5.1 Wipe the skin of your injection site with an alcohol pad to clean it (Figure K).

Warning: Do not blow on or touch the injection site after cleaning.



Figure K

Step 6 Give your Injection

6.1 Remove the needle cap

- Hold the pre-filled pen upwards and pull the needle cap straight off (Figure L).

You may see drops of liquid at the needle

- Throw away the needle cap.

Warning: Do not twist the cap.

Warning: Do not recap the pre-filled pen.

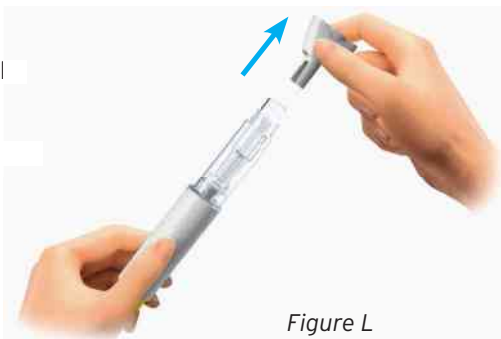


Figure L

6.2 Position the pre-filled pen

- Hold the pre-filled pen so that you can see the transparent syringe housing.
- Place your thumb above (not touching) the yellow injection button (Figure M).



Figure M

- Place the pre-filled pen against your skin at a 90° angle (Figure N).

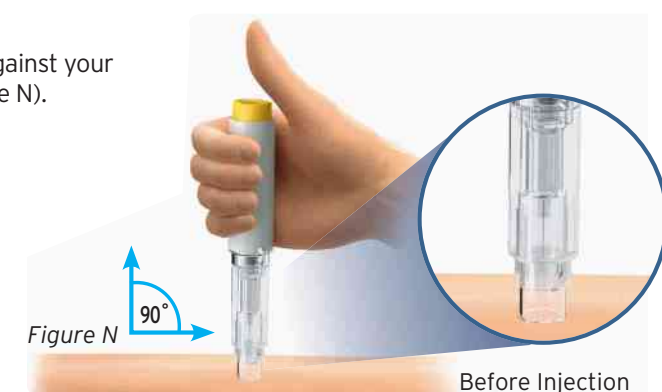


Figure N

Before Injection

- Push and hold the pre-filled pen firmly against your skin until the safety guard is fully depressed. This will unlock the injection button (Figure O).

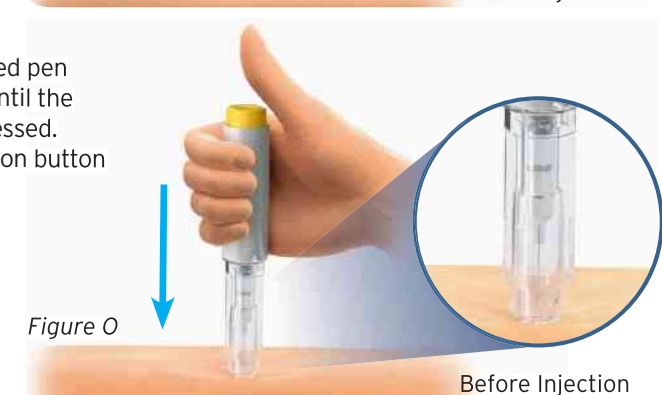


Figure O

Before Injection

6.3 Administer the Injection

- Push the injection button (Figure P). You will hear a loud click, which means the injection has started.
- Continue to HOLD the pre-filled pen firmly.
- WATCH the syringe plunger to make sure it moves all the way down to the bottom (Figure P).

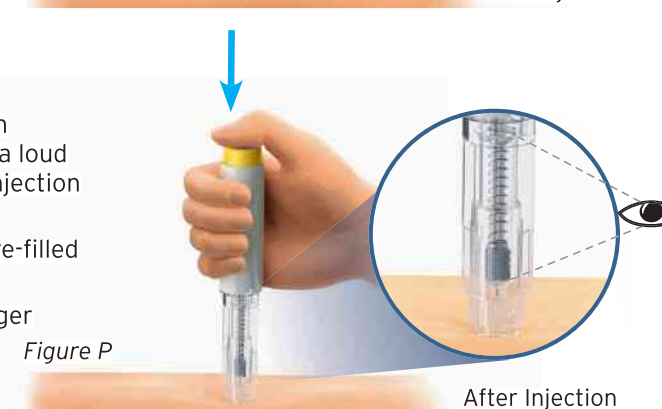


Figure P

After Injection

Warning: Do not lift the pre-filled pen from the skin until the plunger has moved all the way down and all the liquid has been injected.

- When the syringe plunger has moved to the bottom and has stopped moving, continue holding it for 5 seconds.
- Lift the pre-filled pen from your skin (Figure Q).

The safety guard will slide down and lock into place to protect you from the needle (Figure Q).

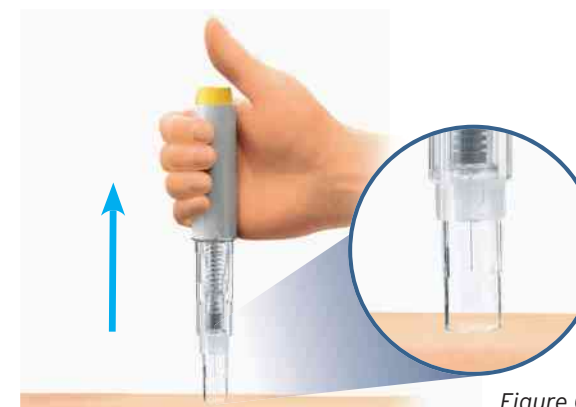


Figure Q

Warning: Call your healthcare professional or pharmacist if you have any problem.

6.4 If there is blood or liquid on the skin, treat the injection site by gently pressing a cotton ball or gauze on the site (Figure R).



Figure R

Step 7 Throw away your Pre-filled Pen

7.1 Throw away your used pre-filled pen in a sharps disposal container right away after use (Figure S).

Warning: Keep your sharps disposal container out of the reach of children.

Warning: Do not throw away the pre-filled pen in your household trash.

If you do not have a sharps disposal container, you may use a household container that is:

- Made of a heavy-duty plastic;
- Can be closed with a tight-fitting, puncture-resistant lid; that will keep sharps from coming out,
- Upright and stable during use,
- Leak-resistant and
- Properly labeled to warn of hazardous waste inside the container.



Figure S

7.2 When your sharps disposal container is almost full, you will need to follow your local guidelines for the right way to dispose of your sharps disposal container.

Do not recycle your used sharps disposal container.

Step 8 Record your Injection

8.1 To help you remember when and where to do your next injection, you should keep a record of the dates and injection sites used for your injections (Figure T).



Figure T

Information for the patient

Idacio®



40 mg solution for injection in pre-filled pen

adalimumab

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Your doctor will also give you a patient reminder card, which contains important safety information that you need to be aware of before you are given Idacio and during treatment with Idacio. Keep this patient reminder card with you during your treatment and for 4 months after your (or your child's) last injection of Idacio.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet (see section 4).

What is in this leaflet

- What Idacio is and what it is used for
- What you need to know before you use Idacio
- How to use Idacio
- Possible side effects
- How to store Idacio
- Contents of the pack and other information
- Instructions for use

1. What Idacio is and what it is used for

Idacio contains the active substance adalimumab, a medicine that acts on your body's immune (defence) system.

Idacio is intended for the treatment of the following inflammatory diseases:

- rheumatoid arthritis,
- polyarticular juvenile idiopathic arthritis,
- enthesitis-related arthritis,
- ankylosing spondylitis,
- axial spondyloarthritis without radiographic evidence of ankylosing spondylitis,
- psoriatic arthritis,
- psoriasis,
- hidradenitis suppurativa,
- Crohn's disease,
- ulcerative colitis and
- non-infectious uveitis

The active ingredient in Idacio, adalimumab, is a monoclonal antibody. Monoclonal antibodies are proteins that attach to a specific target in the body.

The target of adalimumab is another protein called tumour necrosis factor (TNFα), which is present at increased levels in the inflammatory diseases listed above. By attaching to TNFα, Idacio blocks its action and reduces the inflammation in these diseases.

Rheumatoid arthritis

Rheumatoid arthritis is an inflammatory disease of the joints.

Idacio is used to treat rheumatoid arthritis in adults. If you have moderate to severe active rheumatoid arthritis, you may first be given other disease-modifying medicines, such as methotrexate. If these medicines do not work well enough, you will be given Idacio to treat your rheumatoid arthritis.

Idacio can also be used to treat severe, active and progressive rheumatoid arthritis without previous methotrexate treatment.

Idacio can slow down the damage to the cartilage and bone of the joints caused by the disease and improve physical function.

Usually, Idacio is used with methotrexate. If your doctor considers that methotrexate is inappropriate, Idacio can be given alone.

Polyarticular juvenile idiopathic arthritis and enthesitis-related arthritis

Polyarticular juvenile idiopathic arthritis and enthesitis-related arthritis are inflammatory diseases of the joints that usually first appear in childhood.

Idacio is used to treat polyarticular juvenile idiopathic arthritis in children and adolescents aged 2 to 17 years and enthesitis-related arthritis in children and adolescents aged 6 to 17 years. Patients may first be given other disease-modifying medicines, such as methotrexate. If these medicines do not work well enough, patients will be given Idacio to treat their polyarticular juvenile idiopathic arthritis or enthesitis-related arthritis.

Ankylosing spondylitis and axial spondyloarthritis without radiographic evidence of ankylosing spondylitis

Ankylosing spondylitis and axial spondyloarthritis without radiographic evidence of ankylosing spondylitis, are inflammatory diseases of the spine.

Idacio is used in adults to treat these conditions. If you have ankylosing spondylitis or axial spondyloarthritis without radiographic evidence of ankylosing spondylitis, you will first be given other medicines. If these medicines do not work well enough, you will be given Idacio to reduce the signs and symptoms of your disease.

Psoriatic arthritis

Psoriatic arthritis is an inflammatory disease of the joints associated with psoriasis.

Idacio is used to treat psoriatic arthritis in adults. Idacio can slow down the damage to the cartilage and bone of the joints caused by the disease and improve physical function.

Plaque psoriasis in adults and children

Plaque psoriasis is an inflammatory skin condition that causes red, flaky, crusty patches of skin covered with silver scales. Plaque psoriasis can also affect the nails, causing them to crumble, become thickened and lift away from the nail bed which can be painful. Psoriasis is believed to be caused by a problem with the body's immune system that leads to an increased production of skin cells.

Idacio is used to treat moderate to severe plaque psoriasis in adults. Idacio is also used to treat severe plaque psoriasis in children and adolescents adolescents aged 4 to 17 years for whom medicines applied to the skin and treatment with UV light have either not worked very well or are not suitable.

Hidradenitis suppurativa in adults and adolescents

Hidradenitis suppurativa (sometimes called acne inversa) is a long-term and often painful inflammatory skin disease. Symptoms may include tender nodules (lumps) and abscesses (boils) that may leak pus. It most commonly affects scarring areas of the skin, such as under the breasts, the armpits, inner thighs, groin and buttocks. Scarring may also occur in affected areas.

Idacio is used to treat hidradenitis suppurativa in adults and adolescents from 12 years of age. Idacio can reduce the number of nodules and abscesses you have, and the pain that is often associated with the disease. You may first be given other medicines. If these medicines do not work well enough, you will be given Idacio.

Crohn's disease in adults and children

Crohn's disease is an inflammatory disease of the gut.

Idacio is used to treat Crohn's disease in adults and children aged 6 to 17 years. If you have Crohn's disease you will first be given other medicines. If you do not respond well enough to these medicines, you will be given Idacio to reduce the signs and symptoms of your Crohn's disease.

Ulcerative colitis

Ulcerative colitis is an inflammatory disease of the bowel.

Idacio is used to treat ulcerative colitis in adults. If you have ulcerative colitis you will first be given other medicines. If these medicines do not work well enough, you will be given Idacio to reduce the signs and symptoms of your disease.

Non-infectious uveitis in adults and children

Non-infectious uveitis is an inflammatory disease affecting certain parts of the eye. The inflammation leads to a decrease of vision and/or the presence of floaters in the eye (black dots or wispy lines that move across the field of vision). Idacio works by reducing this inflammation.

- Idacio is used to treat:
- adults with non-infectious uveitis with inflammation affecting the back of the eye
- children from 2 years of age with chronic non-infectious uveitis with inflammation affecting the front of the eye.

2. What you need to know before you use Idacio

Do not use Idacio

- if you are allergic to adalimumab or any of the other ingredients of this medicine (listed in section 6).
- if you have a severe infection, including tuberculosis, sepsis (blood poisoning) or other opportunistic infections (unusual infections associated with a weakened immune system). It is important that you tell your doctor if you have symptoms of infections, e.g. fever, wounds, feeling tired, dental problems (see "Warnings and precautions").
- if you have moderate or severe heart failure. It is important to tell your doctor if you have had or have a serious heart condition (see "Warnings and precautions").

Warnings and precautions

Talk to your doctor or pharmacist before using Idacio

Allergic reaction

- If you have allergic reactions with symptoms such as chest tightness, wheezing, dizziness, swelling or rash do not inject more Idacio and contact your doctor immediately since, in rare cases, these reactions can be life threatening.

Infection

- If you have an infection, including long-term or localised infection (for example, leg ulcer) consult your doctor before starting Idacio. If you are unsure, contact your doctor.
- You might get infections more easily while you are receiving Idacio treatment. This risk may increase if your lung function is reduced. These infections may be more serious and include tuberculosis, infections caused by viruses, fungi, parasites or bacteria, or other unusual infectious organisms and sepsis (blood poisoning). In rare cases, these infections may be life-threatening. It is important to tell your doctor if you get symptoms such as fever, wounds, feeling tired or dental problems. Your doctor may recommend temporarily stopping Idacio.

Tuberculosis (TB)

As cases of tuberculosis have been reported in patients treated with adalimumab, your doctor will check you for signs and symptoms of tuberculosis before starting Idacio. This will include a thorough medical evaluation including your medical history and screening tests (for example chest X-ray and a tuberculin test). The conduct and results of these tests should be recorded on your patient reminder card. It is very important that you tell your doctor if you have ever had tuberculosis, or if you have

been in close contact with someone who has had tuberculosis. Tuberculosis can develop during therapy even if you have had preventative treatment for tuberculosis. If symptoms of tuberculosis (persistent cough, weight loss, listlessness, mild fever), or any other infection appear during or after therapy tell your doctor immediately.

Travel/recurrent infection

- Tell your doctor if you have lived or travelled in regions where fungal infections such as histoplasmosis, coccidioidomycosis or blastomycosis are common.
- Tell your doctor if you have a history of recurrent infections or other conditions that increase the risk of infections.

Hepatitis B virus

- Tell your doctor if you are a carrier of the hepatitis B virus (HBV), if you have active HBV infection or if you think you might be at risk of contracting HBV. Your doctor should test you for HBV. Adalimumab can reactivate HBV infection in people who carry this virus. In some rare cases, especially if you are taking other medicines that suppress the immune system, reactivation of HBV infection can be life-threatening.

Age over 65 years

- If you are over 65 years you may be more susceptible to infections while taking Idacio. You and your doctor should pay special attention to signs of infection while you are being treated with Idacio. It is important to tell your doctor if you get symptoms of infections, such as fever, wounds, feeling tired or dental problems.

Surgery or dental procedures

- If you are about to have surgery or dental procedures tell your doctor that you are taking Idacio. Your doctor may recommend temporarily stopping Idacio.

Demyelinating disease

- If you have or develop demyelinating disease (a disease that affects the insulating layer around the nerves, such as multiple sclerosis), your doctor will decide if you should receive or continue to receive Idacio. Tell your doctor immediately if you get symptoms like changes in your vision, weakness in your arms or legs or numbness or tingling in any part of your body.

Vaccine

- Certain vaccines contain living but weakened forms of disease-causing bacteria or viruses and should not be given during treatment with Idacio in case they cause infections. Check with your doctor before you receive any vaccines. It is recommended that, if possible, children be given all the scheduled vaccinations for their age before they start treatment with Idacio. If you receive Idacio while you are pregnant, your baby may be at higher risk for getting an infection for up to about five months after the last dose you received during pregnancy. It is important that you tell your baby's doctors and other health care professionals about your Idacio use during your pregnancy so they can decide when your baby should receive any vaccine.

Heart failure

- It is important to tell your doctor if you have had or have a serious heart condition. If you have mild heart failure and you are being treated with Idacio, your heart failure status must be closely monitored by your doctor. If you develop new or worsening symptoms of heart failure (e.g. shortness of breath, or swelling of your feet), you must contact your doctor immediately.

Fever, bruising, bleeding or looking pale

- In some patients the body may fail to produce enough of the blood cells that fight off infections or help you to stop bleeding. If you develop a fever that does not go away, or you bruise or bleed very easily or look very pale, call your doctor right away. Your doctor may decide to stop treatment.

Cancer

- There have been very rare cases of certain kinds of cancer in children and adults taking adalimumab or other TNFα blockers. People with more serious rheumatoid arthritis who have had the disease for a long time may have a higher than average risk of getting lymphoma and leukaemia (cancers that affect blood cells and bone marrow). If you take Idacio the risk of getting lymphoma, leukaemia, or other cancers may increase. On rare occasions, a specific and severe type of lymphoma, has been observed in patients taking adalimumab. Some of those patients were also treated with the medicines azathioprine or mercaptopurine. Tell your doctor if you are taking azathioprine or mercaptopurine with Idacio.
- In addition cases of non-melanoma skin cancer have been observed in patients taking adalimumab. If new areas of damaged skin appear during or after treatment or if existing marks or areas of damage change appearance, tell your doctor.
- There have been cases of cancers, other than lymphoma, in patients with a specific type of lung disease called chronic obstructive pulmonary disease (COPD) treated with another TNFα blocker. If you have COPD, or are a heavy smoker, you should discuss with your doctor whether treatment with a TNFα blocker is appropriate for you.
- On rare occasions, treatment with Idacio could result in lupus-like syndrome. Contact your doctor if symptoms such as persistent unexplained rash, fever, joint pain or tiredness occur.

Children and adolescents

- Vaccinations: if possible children should be up to date with all vaccinations before using Idacio.
- Do not give Idacio to children with polyarticular juvenile idiopathic arthritis below the age of 2 years.
- Do not use the 40 mg pre-filled syringe or 40 mg pre-filled pen if doses other than 40 mg are recommended.

Other medicines and Idacio

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Idacio can be taken together with methotrexate or certain disease-modifying anti-rheumatic agents (sulfasalazine, hydroxychloroquine, leflunomide and injectable gold preparations), corticosteroids or pain medications including non-steroidal anti-inflammatory drugs (NSAIDs).

You should not take Idacio with medicines containing the active substances anakinra or abatacept due to increased risk of serious infection. The combination of adalimumab as well as other TNF-antagonists and anakinra or abatacept is not recommended based upon the possible increased risk for infections, including serious infections and other potential pharmacological interactions. If you have questions, please ask your doctor.

Pregnancy and breast-feeding

If you think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You are advised to avoid becoming pregnant and must use adequate contraception while using Idacio and for at least 5 months after the last Idacio injection. If you become pregnant, you should see your doctor.

Idacio should only be used during a pregnancy if needed.

According to a pregnancy study, there was no higher risk of birth defects when the mother had received adalimumab during pregnancy compared with mothers with the same disease who did not receive adalimumab.

Idacio can be used during breast-feeding.

If you receive Idacio during your pregnancy, your baby may have a higher risk for getting an infection. It is important that you tell your baby's doctors and other health care professionals about your Idacio use during your pregnancy before the baby receives any vaccine (for more information see section on vaccination).

Driving and using machines

Idacio may have a minor influence on your ability to drive, cycle or use machines. Room spinning sensation (vertigo) and vision disturbances may occur after taking Idacio.

Idacio contains sodium

This medicine contains less than 1mmol of sodium (23 mg) per 0.8 ml dose, that is to say essentially 'sodium-free'.

3. How to use Idacio

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Idacio is injected under the skin (subcutaneous use). Patients requiring a dose less than 40 mg should use the 40 mg vial presentation of Idacio.

The recommended doses for Idacio in each of the approved uses are shown in the following table.

Rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis or axial spondyloarthritis without radiographic evidence of ankylosing spondylitis		
Age or body weight	How much and how often to take?	Notes
Adults	40 mg every other week	In rheumatoid arthritis, methotrexate is continued while using Idacio. If your doctor decides that methotrexate is inappropriate, Idacio can be given alone. <p>If you have rheumatoid arthritis and you do not receive methotrexate with your Idacio therapy, your doctor may decide to give Idacio 40 mg every week or 80 mg every other week.</p>

Polyarticular juvenile idiopathic arthritis		
Age or body weight	How much and how often to take?	Notes
Children, adolescents and adults from 2 years of age weighing 30 kg or more	40 mg every other week	Not applicable
Children and adolescents from 2 years of age weighing 10 kg to less than 30 kg	20 mg every other week	Not applicable
Enthesitis-related arthritis		
Age or body weight	How much and how often to take?	Notes
Children, adolescents and adults from 6 years of age weighing 30 kg or more	40 mg every other week	Not applicable
Children and adolescents from 6 years of age weighing 15 kg to less than 30 kg	20 mg every other week	Not applicable
Plaque psoriasis		
Age or body weight	How much and how often to take?	Notes

Age or body weight	How much and how often to take?	Notes
Adults	Initial dose of 80 mg (as two 40 mg injections in one day), followed by 40 mg given every other week starting one week after the initial dose. <p>You should continue to inject Idacio for as long as your doctor has told you.</p>	If this dose does not work well enough, your doctor may increase the dose to 40 mg every week or 80 mg every other week.
Children and adolescents from 4 to 17 years of age weighing 30 kg or more	Initial dose of 40 mg, followed by 40 mg one week later. <p>Thereafter, the usual dose is 40 mg every other week.</p>	Not applicable
Children and adolescents from 4 to 17 years of age weighing 15 kg to less than 30 kg	Initial dose of 20 mg, followed by 20 mg one week later. <p>Thereafter, the usual dose is 20 mg every other week.</p>	Not applicable

Hidradenitis suppurativa		
Age or body weight	How much and how often to take?	Notes
Adults	Initial dose of 160 mg (as four 40 mg injections in one day or two 40 mg injections per day for two consecutive days), followed by an 80 mg dose (as two 40 mg injections on the same day) two weeks later. After two further weeks, continue with a dose of 40 mg every week or 80 mg every other week, as prescribed by your doctor.	It is recommended that you use an antiseptic wash daily on the affected areas.
Adolescents from 12 to 17 years of age weighing 30 kg or more	Initial dose of 80 mg (as two 40 mg injections in one day), followed by 40 mg every other week starting one week later.	If this dose does not work well enough, your doctor may increase the dose frequency to 40 mg every week or 80 mg every other week. <p>It is recommended that you use an antiseptic wash daily on the affected areas.</p>

Crohn's disease		
Age or body weight	How much and how often to take?	Notes
Children, adolescents and adults from 6 years of age weighing 40 kg or more	Initial dose of 80 mg (as two 40 mg injections in one day), followed by 40 mg two weeks later. <p>If a faster response is required, your doctor may prescribe an initial dose of 160 mg (as four 40 mg injections in one day or two 40 mg injections per day for two consecutive days) followed by 80 mg (as two 40 mg injections in one day) two weeks later.</p> <p>Thereafter, the usual dose is 40 mg every other week.</p>	If this dose does not work well enough, your doctor may increase the dose frequency to 40 mg every week or 80 mg every other week.
Children and adolescents from 6 to 17 years of age weighing less than 40 kg	Initial dose of 40 mg, followed by 20 mg two weeks later. <p>If a faster response is required, your doctor may prescribe a first dose of 80 mg (two 40 mg injections in one day), followed by 40 mg two weeks later.</p> <p>Thereafter, the usual dose is 20 mg every other week.</p>	If this dose does not work well enough, your doctor may increase the dose frequency to 20 mg every week.

Ulcerative colitis

Age or body weight	How much and how often to take?	Notes
Adults	Initial dose of 160 mg (as four 40 mg injections in one day or as two 40 mg injections per day for two consecutive days), followed by 80 mg (as two 40 mg injections in one day) two weeks later. <p>Thereafter, the usual dose is 40 mg every other week.</p>	If this dose does not work well enough, your doctor may increase the dosage to 40 mg every week or 80 mg every other week.

Non-infectious uveitis

Age or body weight	How much and how often to take?	Notes
• Adults	Initial dose of 80 mg (as two 40 mg injections), followed by 40 mg every other week starting one week after the initial dose. <p>You should continue to inject Idacio for as long as your doctor has told you.</p>	Corticosteroids or other medicines that influence the immune system may be continued while using Idacio. Idacio can also be given alone.
Children and adolescents from 2 years of age weighing less than 30 kg	20 mg every other week	Your doctor may prescribe an initial dose of 40 mg which may be administered one week prior to the start of the usual dose. <p>Idacio is recommended for use in combination with methotrexate.</p>
Children and adolescents from 2 years of age weighing at least 30 kg	40 mg every other week	Your doctor may also prescribe an initial dose of 80 mg which may be administered one week prior to the start of the usual dose. <p>Idacio is recommended for use in combination with methotrexate.</p>

Method and route of administration

Idacio is administered by injection under the skin (by subcutaneous injection).

Detailed instructions on how to inject Idacio are provided in section 7 "Instructions for use".

If you use more Idacio than you should

If you accidentally inject Idacio more frequently than you should, call your doctor or pharmacist and explain that you have taken more than required. Always take the outer carton of the medicine with you, even if it is empty.

If you forget to use Idacio

If you forget to give yourself an injection, you should inject the next dose of Idacio as soon as you remember. Then take your next dose as you would have on your originally scheduled day, had you not forgotten a dose.

If you stop using Idacio

The decision to stop using Idacio should be discussed with your doctor. Your symptoms may return upon stopping treatment.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Most side effects are mild to moderate. However, some may be serious and require treatment. Side effects may occur up to 4 months or more after the last Idacio injection.

Seek medical attention urgently, if you notice any of the following signs of allergic reaction or heart failure:

- severe rash, hives;
- swollen face, hands, feet;
- trouble breathing, swallowing;
- shortness of breath with exertion or upon lying down or swelling of the feet.

Tell your doctor as soon as possible, if you notice any of the following:

- signs and symptoms of infection such as fever, feeling sick, wounds, dental problems, burning on urination, feeling weak or tired or coughing;
- symptoms of nerve problems such as tingling, numbness, double vision or arm or leg weakness;
- signs of skin cancer such as a bump or open sore that doesn't heal;
- signs and symptoms suggestive of blood disorders such as persistent fever, bruising, bleeding, paleness.

The following side effects have been observed with adalimumab:

Very common (may affect more than 1 in 10 people)

- injection site reactions (including pain, swelling, redness or itching);
- respiratory tract infections (including cold, runny nose, sinus infection, pneumonia);
- headache;
- abdominal (belly) pain;
- nausea and vomiting;
- rash;
- pain in the muscles.

Common (may affect up to 1 in 10 people)

- serious infections (including blood poisoning and influenza);
- intestinal infections (including gastroenteritis);
- skin infections (including cellulitis and shingles);
- ear infections;
- mouth infections (including tooth infections and cold sores);
- reproductive tract infections;
- urinary tract infection;
- fungal infections;
- joint infections;
- benign tumours;
- skin cancer;
- allergic reactions (including seasonal allergy);
- dehydration;
- mood swings (including depression);
- anxiety;
- difficulty sleeping;
- sensation disorders such as tingling, prickling or numbness;
- migraine;
- symptoms of nerve root compression (including low back pain and leg pain);
- vision disturbances;
- eye inflammation;
- inflammation of the eye lid and eye swelling;
- vertigo (sensation of room spinning);
- sensation of heart beating rapidly;
- high blood pressure;
- flushing;
- haematoma (a solid swelling with clotted blood);
- cough;
- asthma;
- shortness of breath;
- gastrointestinal bleeding;
- dyspepsia (indigestion, bloating, heart burn);
- acid reflux disease;
- sicca syndrome (including dry eyes and dry mouth);
- itching;
- itchy rash;
- bruising;
- inflammation of the skin (such as eczema);
- breaking of finger nails and toe nails;
- increased sweating;
- hair loss;
- new onset or worsening of psoriasis;
- muscle spasms;
- blood in urine;
- kidney problems;
- chest pain;
- oedema (a build-up of fluid in the body which causes the affected tissue to swell);
- fever;

- reduction in blood platelets which increases risk of bleeding or bruising;
- impaired healing.

- Uncommon** (may affect up to 1 in 100 people)
- unusual infections (which include tuberculosis and other infections) that occur when resistance to disease is lowered;
- neurological infections (including viral meningitis);
- eye infections;
- bacterial infections;
- diverticulitis (inflammation and infection of the large intestine);
- cancer, including cancer that affects the lymph system (lymphoma) and melanoma (a type of skin cancer);
- immune disorders that could affect the lungs, skin and lymph nodes (most commonly as a condition called sarcoidosis);
- vasculitis (inflammation of blood vessels);
- tremor;
- neuropathy (nerve damage);
- stroke;
- double vision;
- hearing loss, buzzing;
- sensation of heart beating irregularly such as skipped beats;
- heart problems that can cause shortness of breath or ankle swelling;
- heart attack;
- a sac in the wall of a major artery, inflammation and clot of a vein, blockage of a blood vessel;
- lung diseases causing shortness of breath (including inflammation);
- pulmonary embolism (blockage in an artery of the lung);
- pleural effusion (abnormal collection of fluid in the pleural space);
- inflammation of the pancreas which causes severe pain in the abdomen and back;
- difficulty in swallowing;
- facial oedema (swelling);
- gallbladder inflammation, gallbladder stones;
- fatty liver (build-up of fat in liver cells);
- night sweats;
- scar;
- abnormal muscle breakdown;
- systemic lupus erythematosus (an immune disorder including inflammation of skin, heart, lung, joints and other organ systems);
- sleep interruptions;
- impotence;
- inflammations.