

Product name: IDACIO 40 mg VIAL	Territory: UK
Type of packaging: Leaflet	Dosage: 40 mg
Material number: N09xxxxxG	2-D-Matrix-Code: -
Pharma-Code (Laetus): -	EAN-Code: -
Dimension: 704 x 425 mm	Font: Interstate
	Size: 7

Colours:	Indication only – not to be printed:
• Black	
• Cyan	
• Magenta	
• Yellow	

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Template:	

Operator: Christina Fraueneder

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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.



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

Important Information

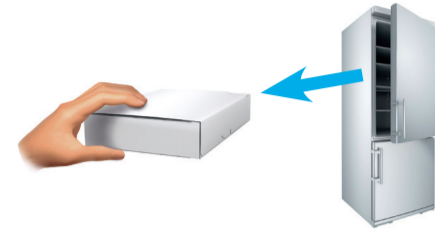
- Only use Idacio Vial Kit if your healthcare professional has trained you how to use it correctly.
- Idacio Vial Kit is for single use only.
- Children are not allowed to inject themselves and injection must be done by a trained adult.
- Keep all components of the Idacio Vial Kit and the sharps disposal 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 28 days.

Step 1 Gather supplies and check for damages

1.1 Remove the Idacio Vial Kit from the refrigerator.

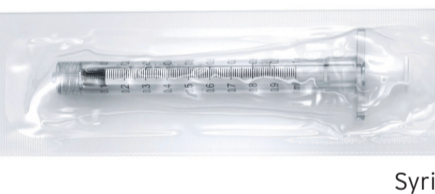


1.2 Leave the kit at room temperature for at least 30 minutes to allow the medicine to warm up. Injecting cold medicine may be painful.



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.



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 expiry date.



Warning: Do not use the vial if:

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

2.3 Check the liquid to make sure that:



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.

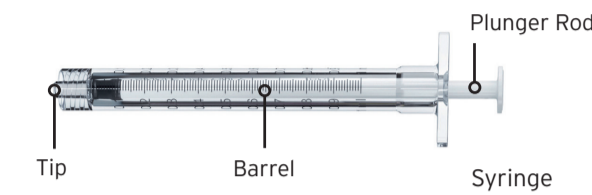


2.8 Hold the vial and lift the packaging off. To ensure the adapter remains on top of the vial, hold the packaging by the outer rim.



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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.

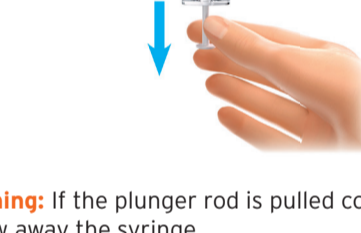
3.2 Hold the vial adapter, insert the syringe tip into it and screw to connect.



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.

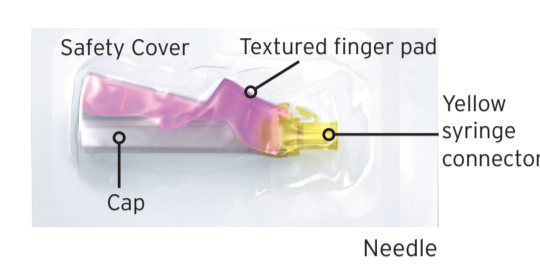


3.7 Place the syringe on a clean, flat surface.

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.

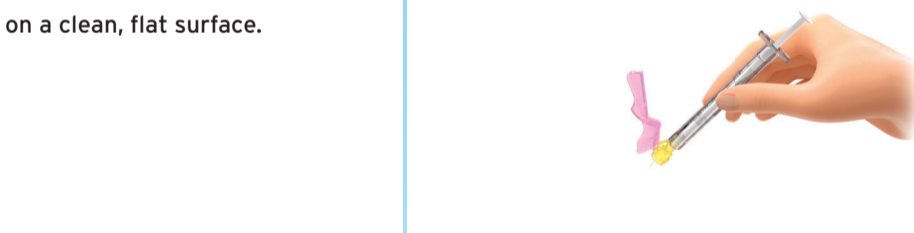
Warning: Do not remove the clear needle cap.

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.

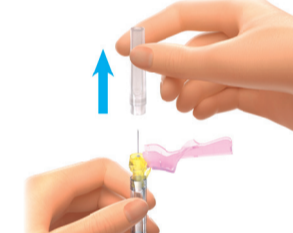
Warning: Do not inject into an area that is sore (tender), bruised, red, hard, scarred or where there are stretch marks.

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°.

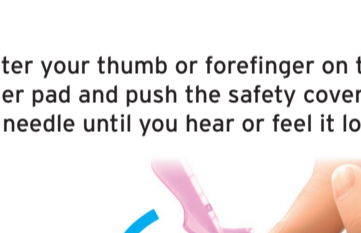


Note: With experience, you will find the angle (between 45° and 90°) that is most comfortable for you and the child.

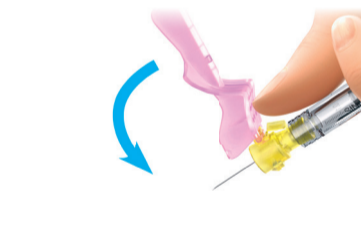
6.3 Gently push the white plunger rod all the way down until the syringe is empty.



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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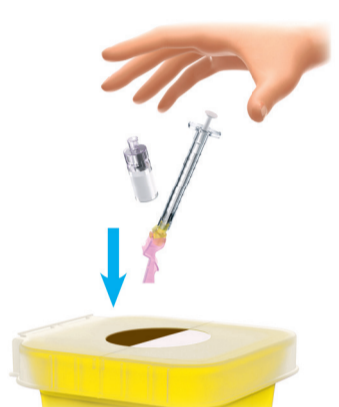
Step 7 Record injection and dispose components

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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Package leaflet: information for the patient

Idacio®

40 mg/0.8 ml solution for injection for paediatric use

adalimumab



Read all of this leaflet carefully before your 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 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 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 this leaflet

1. What Idacio is and what it is used for
2. What you need to know before your child uses Idacio
3. How to use Idacio
4. Possible side effects
5. How to store Idacio
6. Contents of the pack and other information
7. 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 ulcerative colitis
- paediatric uveitis

The active substance 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.

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 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 ulcerative colitis

Ulcerative colitis is an inflammatory disease of the large intestine. Idacio is used to treat moderate to severe ulcerative colitis 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 medicines 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 injection used 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.

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

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. Thereafter, the usual dose is 40 mg every other week.	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. Thereafter, the usual dose is 20 mg every other week.	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 dose to 40 mg every 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. 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. Thereafter, the usual dose is 40 mg every other week.	If this dose does not work well enough, your child's doctor may increase the dose 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. 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. Thereafter, the usual dose is 20 mg every other week.	If this dose does not work well enough, your child's doctor may increase the dose frequency to 20 mg every week.

Paediatric ulcerative colitis		
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 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. Thereafter, the usual dose is 80 mg every other week.	Patients who turn 18 years of age while on 80 mg every other week, should continue their prescribed dose.
Children and adolescents from 6 to 17 years of age weighing less than 40 kg	Initial dose of 80 mg (as two 40 mg injections in one day), followed by 40 mg (as one 40 mg injection) two weeks later. Thereafter, the usual dose is 40 mg every other week.	Patients who turn 18 years of age while on 40 mg every other week, should continue their prescribed dose.

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 tell 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 a 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:

- allergic 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.

- Rare** (may affect up to 1 in 1,000 people)
- leukaemia (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);
 - lung diseases causing shortness of breath (including inflammation);
 - 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);
- Kaposi's sarcoma, a rare cancer related to infection with human herpes virus 8. Kaposi's sarcoma most commonly appears as purple lesions on the skin;
- liver failure;
- worsening of a condition called dermatomyositis (seen as a skin rash accompanying muscle weakness);
- weight gain for most patients, the weight gain was small).

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 blood cells;
- increased lipids in the blood;
- raised liver enzymes.

Common (may affect up to 1 in 10 people)

- signs and symptoms of infection such as fever, feeling sick, wounds, dental problems, burning on urination, feeling weak or tired or coughing;
- 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 phosphate;
- 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 below:

United Kingdom

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

Ireland

HPRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Idacio

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label /carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C). Do not freeze.

Keep the vial in the outer carton in order to protect from light.

Alternative Storage:

When needed (for example when you are travelling), Idacio may be stored at room temperature (up to 25°C) for a maximum period of 28 days – be sure to protect it from light.