

Idacio 40mg solution for injection, vial kit

Adalimumab (rch)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Idacio.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Idacio against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Read this leaflet carefully before you use Idacio and keep it with the medicine.

You may need to read it again.

What Idacio is used for

Idacio is intended for the treatment of:

- Rheumatoid arthritis

Idacio is used to reduce the signs and symptoms of moderate to severely active rheumatoid arthritis, a painful disease of the joints, as well as to slow down and protect against damage to joints. Signs and symptoms of rheumatoid arthritis include joint pain, tenderness, swelling and stiffness.

- Polyarticular Juvenile Idiopathic Arthritis

Idacio is used for reducing the signs and symptoms of moderately

to severely active polyarticular juvenile idiopathic arthritis, which is an inflammatory disease involving multiple joints, in patients 2 years of age and older.

- Enthesitis-related arthritis

Idacio is used to treat enthesitis-related arthritis, an inflammatory disease that begins before the 16th birthday, in patients from 6 years of age.

- Psoriatic arthritis

Idacio is used to reduce the signs and symptoms, as well as inhibit the progression of joint damage of moderate to severely active psoriatic arthritis, a disease of the joints and skin, with some similarities to rheumatoid arthritis, as well as psoriasis and other factors.

- Ankylosing spondylitis

Idacio is used to reduce the signs and symptoms in patients with active ankylosing spondylitis, an inflammatory disease of the spine. Signs and symptoms of ankylosing spondylitis include back pain and morning stiffness.

- Non-radiographic axial spondyloarthritis

Idacio is used for the treatment of adult patients with severe axial spondyloarthritis without radiographic evidence of ankylosing spondylitis, an inflammatory disease of the spine. Your doctor will check that you have objective signs of inflammation via a blood test or scan, and will prescribe Idacio only if you have not responded well

enough to anti-inflammatory medicines.

- Crohn's Disease

Idacio is used for the treatment of moderate to severe Crohn's disease, an inflammatory disease of the digestive tract, in adults and children aged 6 years and above, to reduce the signs and symptoms of the disease and to induce and maintain periods where the symptoms are no longer present. Idacio can be given to patients who have not responded well enough to conventional therapies, or who have lost response to or are intolerant to infliximab (another medicine used to treat Crohn's disease).

- Ulcerative Colitis

Idacio is used for the treatment of moderate to severe ulcerative colitis an inflammatory bowel disease, in patients who have not responded well enough to conventional therapy or who are intolerant to or have medical contraindications for such therapies.

- Psoriasis

Idacio is used to treat chronic plaque psoriasis, an inflammatory disease of the skin. Plaque psoriasis can also affect nails, causing them to crumble, thicken and lift away from the nail bed which can be painful.

Idacio is used for moderate to severe forms of the disease in adults and severe forms in children and adolescents from 4 years of age who have not responded well enough to topical therapy and

phototherapy, or who cannot be given those treatments.

- Uveitis

Idacio is used to treat adults with non-infectious intermediate, posterior and pan-uveitis, with inflammation affecting the back of the eye and children from 2 years of age with chronic non-infectious anterior uveitis with inflammation affecting the eye. 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. Signs and symptoms include inflammation, vision impairment and pain.

- Hidradenitis suppurativa

Idacio is used for the treatment of adult and adolescents from 12 years of age with active moderate to severe hidradenitis suppurativa (acne inversa), a chronic 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.

The active ingredient in this medicine is adalimumab, a fully human monoclonal antibody. Monoclonal antibodies are proteins made by a type of blood cell to fight a foreign protein in the body. Adalimumab recognises and binds to a specific protein (tumour necrosis factor or TNF-alpha), which is present at increased levels in inflammatory diseases such as rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, enthesitis-related arthritis, psoriatic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, Crohn's disease, ulcerative colitis, psoriasis, hidradenitis suppurativa and uveitis.

Ask your doctor if you have any questions about why this

medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is only available with a doctor's prescription.

The long term effects of adalimumab on the growth and development of children is not known.

Before you use Idacio

When you must not use it

Do not use Idacio if you have:

- **You have an allergy to any medicine containing adalimumab or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include:

- chest tightness
- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- hives, itching or skin rash

- **You have a severe infection** including infection of the bloodstream, active tuberculosis and other infections that can occur when the body's natural defences are lowered.

- **You are already using anakinra (Kineret)** - a medicine for rheumatoid arthritis.

- You have moderate to severe heart failure.

Do not use this medicine after the expiry date printed on the

label / blister / carton or if the packaging is torn or shows signs of tampering.

Return it to your pharmacist for disposal.

Before you use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- an infection, including a long- term or localised infection (for example, leg ulcer)
- a history of recurrent infections or other conditions that increase the risk of infections

- a history of tuberculosis, or if you have been in close contact with someone who has had 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.

As cases of tuberculosis have been reported in patients treated with Idacio, your doctor will check you for signs and symptoms of tuberculosis before starting this medicine. This will include a thorough medical history, a chest x-ray and tuberculin test.

- The hepatitis B virus (HBV) if you are a carrier of, or you have active HBV or you think you might be at risk of contracting HBV. Idacio can cause

reactivation of HBV 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 can be life threatening.

- If you suffer from uveitis, your doctor may check for signs and symptoms of neurologic disease before starting this medicine.
- a fungal infection, or have lived or travelled in countries where some fungal infections are common. These infections may develop or become more severe if you take Idacio.
- multiple sclerosis a disease of the nervous system or other demyelinating disease
- allergic reactions such as chest tightness, wheezing, dizziness, swelling or rash
- blood disorders
- low resistance to disease
- heart conditions including congestive heart failure, heart attack or worsening of existing heart conditions
- cancer or autoimmune disease
- a lung disease called chronic obstructive pulmonary disease
- kidney or liver problems

Tell your doctor if you are scheduled for any vaccines

It is recommended that children, if possible, be brought up to date with all immunisations in agreement with current immunisation guidelines prior to initiating Idacio therapy. Patients receiving Idacio should not

receive live vaccines.

Tell your doctor if you are a psoriasis sufferer who has undergone phototherapy.

Tell your doctor if you are pregnant or plan to become pregnant.

A pregnancy study found that there was no higher risk of birth defects when the mother had used adalimumab during pregnancy, compared with mothers with the same disease who did not use adalimumab.

If you use Idacio during pregnancy, your baby may have a higher risk of getting an infection.

It is important that you tell your baby's doctors and other healthcare professionals about your Idacio use during your pregnancy before the baby receives any vaccine.

Tell your doctor if you are breastfeeding or plan to breastfeed.

If you have not told your doctor or pharmacist about any of the above, tell them before you start using Idacio.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket, naturopath or health food shop.

Some medicines and Idacio may interfere with each other. Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

Tell your doctor if you are currently taking or have previously taken any medicine

that lowers the body's resistance to disease.

Tell your doctor or pharmacist if you are taking anakinra (Kineret) or abatacept (Orencia), other medicines used to treat some forms of arthritis.

Taking the two medicines together may increase the risk of infection.

Idacio can be taken together with other medicines used to treat arthritis, such as: methotrexate, steroids or pain medications including non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen.

Tell your doctor if you are taking any other medicines to treat your condition.

How to use Idacio

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the label or in this leaflet, ask your doctor or pharmacist for help.

Always use Idacio exactly as your doctor has instructed you.

You should check with your doctor or pharmacist if you are unsure.

How much to use

Adults

Rheumatoid Arthritis & Psoriatic Arthritis & Ankylosing spondylitis & Non-radiographic axial spondylitis

The usual dose for adults with rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis is one 40mg injection fortnightly.

Crohn's disease & Ulcerative Colitis

The usual dose for adults with Crohn's disease or ulcerative colitis is an initial dose of 160mg (given as four injections on one day or two injections a day over two days), followed by 80mg two weeks later (given two 40mg injections in one day) then 40mg starting two weeks later and continuing every fortnight.

For adults with Crohn's disease or ulcerative colitis, your doctor may increase this ongoing (maintenance) dose to 40 mg every week depending on your response.

Psoriasis & Uveitis

The usual dose for adults with psoriasis or uveitis is an initial dose of 80mg (given as two 40 mg injections in one day), followed by 40mg given fortnightly starting one week after the initial dose.

For adults with psoriasis, depending on your response, your doctor may increase the dose frequency to 40mg every week.

Hidradenitis suppurativa

The usual dose for adults with hidradenitis suppurativa is an initial dose of 160mg (given as four injections in one day or two injections per day over two consecutive days), followed by an 80mg dose (as two injections in one day) two weeks later. After a further two weeks, continue with a dose of 40mg every week.

Your doctor may prescribe other medicines for your condition to take with this medicine.

Children

Patients requiring a dose less than 40mg should use the 40mg vial presentation of Idacio.

Juvenile Idiopathic Arthritis

For children with polyarticular juvenile idiopathic arthritis, 2 years and older, or enthesitis-related arthritis, 6 years and older

- with a body weight of 30 kg or above: the usual dose is 40 mg given fortnightly as a single dose.
- with a body weight of 15 kg to below 30 kg the recommended dose is 20 mg fortnightly.
- With a body weight of 10 kg to below 15 kg the recommended dose is 10mg fortnightly.

Crohn's Disease

The usual dose for children with Crohn's disease depends on body weight and the severity of disease.

- with a body weight of 40 kg or above: the starting dose is 160 mg (given as four 40 mg injections in one day OR as two 40 mg injections per day over two consecutive days), followed by 80 mg two weeks later (given as two 40 mg injections given in one day). After a further two weeks (maintenance dose), continue with 20 mg or 40 mg every fortnight, (depending on severity of disease).
- With a body weight of less than 40 kg, the starting dose is 80 mg (given as two 40 mg injections in one day), followed by 40 mg two weeks later (given as one 40 mg injection). After a further two weeks (maintenance dose), continue with 10 mg or 20 mg every fortnight depending on severity of disease.

Depending on your response, your doctor may increase the ongoing (maintenance) dose frequency to weekly.

Psoriasis

The usual dose for children with psoriasis depends on body weight.

- With a body weight of 30 kg or above, the usual dose is 40 mg given once weekly for the first two weeks, then fortnightly.
- With a body weight of less than 30 kg, the usual dose is 20 mg given once weekly for the first two weeks, then fortnightly.

If Idacio has no effect on the child's condition after 16 weeks, your doctor may tell you to stop using Idacio.

Uveitis

For children with non-infectious anterior uveitis aged 2 years or older, the dose depends on body weight.

- With a body weight of 30 kg or more, the usual dose is 40 mg fortnightly with methotrexate. Your child's doctor may also prescribe an initial dose of 80 mg which may be administered one week prior to the start of the usual dose.
- With a body weight of less than 30 kg, the usual dose is 20 mg fortnightly with methotrexate. Your child's doctor may also prescribe an initial dose of 40 mg which may be administered one week prior to the start of the usual dose.

Your doctor may prescribe other medicines for your child's condition to take with this medicine.

Hidradenitis suppurativa

The usual dose for adolescents (from 12 years, weighing at least 30 kg) with hidradenitis suppurativa is an initial dose of 80 mg (two 40 mg injections in one day), followed by 40 mg fortnightly starting one week later. If you have an inadequate response, your doctor

may increase the dose frequency to 40 mg every week.

It is recommended you use an antiseptic wash daily on the affected areas.

How to use it

If you are using the Idacio vial kit syringe



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.

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.

Warning: 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.



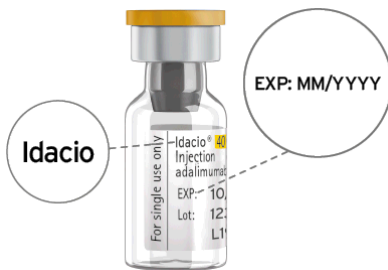
Step 2 Prepare Vial

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.

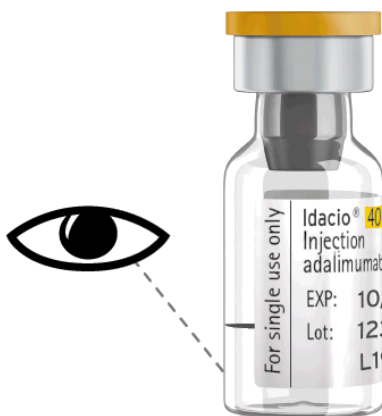


Warning: Do not use the vial if:

- 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, colourless, and free of particles.



Warning: Do not use the vial if the liquid is cloudy, coloured 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.



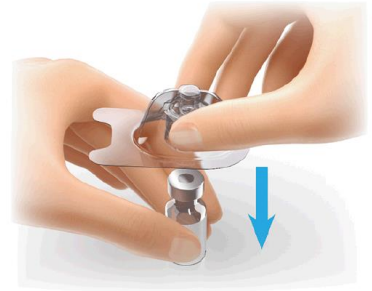
Warning: Do not touch the top of the vial after cleaning.

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.



Step 3 Prepare Syringe



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



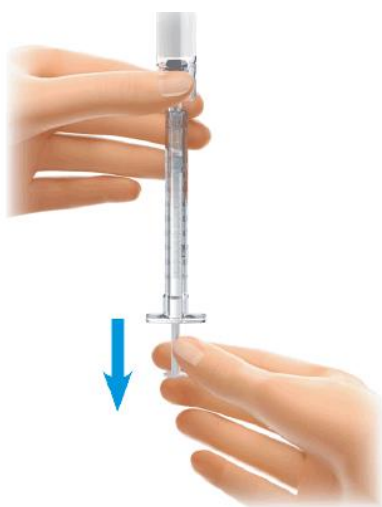
Warning: Do not touch the syringe tip.

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.

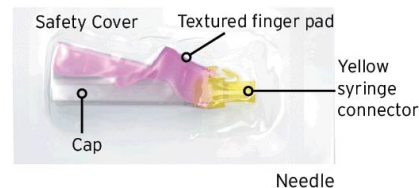
3.6 Turn over the vial and syringe, firmly hold the vial adapter and unscrew the syringe from the vial adapter.



3.7 Place the syringe on a clean, flat surface.

Warning: Do not touch the syringe tip.

Warning: Do not throw the vial away.



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.

Step 4 Prepare Needle



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

4.5 Place the syringe on a clean, flat surface.

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.

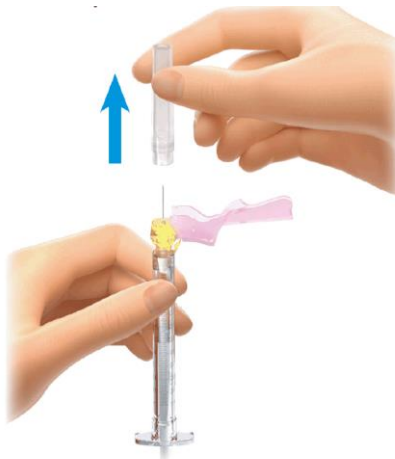
Warning: Do not inject into an area that is sore(tender), bruised, red, hard, scarred or where there are stretch marks.

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



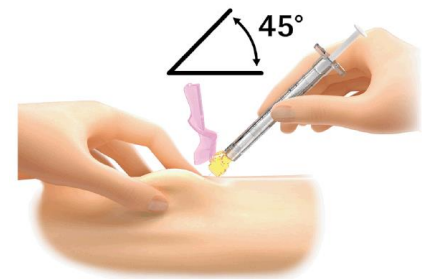
Step 6 Give Injection

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.

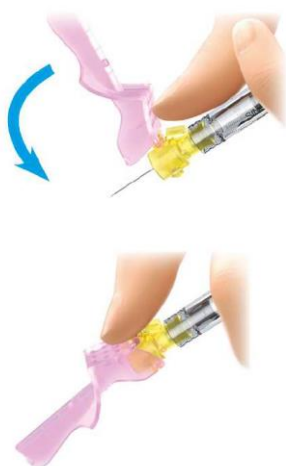


6.4 Remove the needle from the skin, being careful to pull it out at the same angle that it was inserted.

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.

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 labelled 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.

How long to use it

Keep using Idacio for as long as your doctor tells you.

Idacio will not cure your condition but should help control your symptoms.

Ask your doctor if you are not sure how long to take this medicine for.

If you forget to take it

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

Do not try to make up for missed doses by taking more than one dose at a time.

This may increase the chance of getting an unwanted side effect.

If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.

If you are not sure what to do, ask your doctor or pharmacist.

If you take too much (overdose)

If you accidentally inject Idacio more frequently than told to by your doctor, immediately

telephone your doctor or the Poisons Information Centre (Telephone 0800 764 766) or go to Accident and Emergency at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention. Always take the outer carton of the medicine with you.

While you are using IDACIO

Things you must do

Check with your doctor before you receive any vaccines.

It is recommended that children, if possible, be brought up to date with all immunisations in agreement with current immunisation guidelines prior to initiating Idacio therapy.

Some vaccines, such as yellow fever vaccine, should not be given while receiving Idacio.

If you become pregnant while using Idacio, tell your doctor immediately.

If you are about to be started on any new medicine, tell your doctor you are using Idacio.

Tell all doctors, dentists, and pharmacists who are treating you that you are using Idacio.

If you are going to have surgery, tell the surgeon or anaesthetist that you are using Idacio. Your doctor may recommend temporary discontinuation of Idacio.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not give Idacio to anyone else, even if they have the same condition as you.

Do not use Idacio to treat any other complaints unless your doctor tells you to.

Do not stop taking Idacio, without checking with your doctor.

Do not take Idacio and anakinra (Kineret) together.

Do not take Idacio and abatacept (Orencia) together.

Anakinra and abatacept are other medicines used to treat certain forms of arthritis.

Things to be careful of

Tell your doctor if you get symptoms such as fever, wounds, feeling tired or dental problems.

You might get infections more easily while you are receiving Idacio treatment. These infections may be serious and include tuberculosis, infections caused by viruses, fungi or bacteria, or other infections or poisoning of the blood (sepsis) that may, in rare cases, be life-threatening.

Your doctor may recommend temporary discontinuation of Idacio.

Be careful driving or operating machinery until you know how Idacio affects you.

The effects on your ability to drive and use machines whilst taking this medicine are not known.

Side Effects

Tell your doctor as soon as possible if you have any problems while using Idacio, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. You may need medical attention if you get some of the side-effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist any questions you may have.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you experience any of the following:

- Signs of an allergic reaction such as:
 - Chest tightness
 - Shortness of breath, wheezing or difficulty breathing
 - Swelling of the face, lips, tongue or other parts of the body
 - Hives, itching or skin rash
- Shortness of breath with exertion or upon lying down or swelling of the feet
- signs and symptoms suggestive of blood disorders such as persistent fever, bruising, bleeding, paleness

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are uncommon.

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

- Signs of tuberculosis such as persistent cough, weight loss, listlessness, fever
- Signs of infection such as fever, malaise, wounds, dental problems, burning on urination

You might get infections more easily while you are receiving Idacio treatment.

- Signs of nervous system disorders such as numbness or tingling throughout your body, arm or leg weakness, double vision

- Signs of soft tissue infection, such as a bump or open sore that doesn't heal

The above list includes serious side effects. You may need urgent medical attention. Serious side effects are rare.

Tell your doctor if you notice any of the following and they worry you:

- Injection site reactions (including pain, swelling, redness or itching)
- Upper respiratory tract infections (including cold, runny nose, sinus infection, sore throat)
- Lower respiratory tract infections (such as bronchitis, pneumonia)
- Headache, dizziness, vertigo, sensation disorders
- Increased cough, sore throat
- Abdominal symptoms such as nausea, vomiting, abdominal pain,
- Rash, itching
- Fatigue
- Mouth inflammation and ulcers
- Muscle or bone pain
- Viral infections (including the flu, cold sore blisters, chicken pox and shingles)
- Bacterial infections (including Urinary Tract Infection)
- Fungal Infections
- Changes in mood, feeling low or anxious

The above list includes the more common side effects of Idacio. They are usually mild and short lived.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may occur in some people.

There have been cases of certain kinds of cancer in patients taking Idacio or other TNF blockers. People with more serious rheumatoid arthritis that have had

the disease for a long time may have a higher chance of getting a kind of cancer that affects the lymph system, called lymphoma, or that affects the blood, called leukaemia. If you take Idacio your risk 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 azathioprine or 6-mercaptopurine. In addition cases of skin cancer have been observed in patients taking adalimumab. If new skin lesions appear during or after therapy or if existing lesions 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 TNF blocker. If you have COPD, or are a heavy smoker, you should discuss with your doctor whether treatment with a TNF blocker is appropriate for you.

After using IDACIO

Storage

Keep your vial in the pack until it is time to use it.

Keep Idacio in a refrigerator (2°C to 8°C). Do not freeze.

Keep Idacio in the refrigerator in some way children cannot get to it.

Keep the medicine at the right temperature when you travel.

This is important when travelling by car, bus, train, plane or any other form of transport.

If needed, for example when traveling, the Idacio Vial Kit can be stored at room temperature for up to 14 days.

Once removed from the refrigerator and stored at room temperature,

the syringe must be used within 14 days or discarded, even if it is returned to the refrigerator.

Write down the date you first remove the vial from the refrigerator on the label, so you can check how long it has been.

Disposal

After injecting Idacio, immediately throw away the used syringe in a special 'sharps' container as instructed by your doctor, nurse or pharmacist. If your doctor tells you to stop using Idacio or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product Description

What it looks like

Idacio is a clear, colourless solution.

Ingredients

Adalimumab
 Monobasic sodium phosphate dihydrate
 Dibasic sodium phosphate dihydrate
 Mannitol
 Sodium chloride
 Citric acid monohydrate
 Sodium citrate dihydrate
 Polysorbate 80
 Sodium hydroxide (for pH adjustment)
 Water for injections

Supplier

Idacio is supplied in New Zealand by:

Fresenius Kabi New Zealand Limited c/o GNZZ
 HSBC Tower, Level 14, 188 Quay Street
 Auckland 1010, New Zealand
 Freecall: 0800 144 892

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