

## **Package leaflet: Information for the patient**

### **Idacio 40 mg solution for injection in pre-filled syringe**

adalimumab

**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**

1. What Idacio is and what it is used for
2. What you need to know before you use 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:

- rheumatoid arthritis,
- polyarticular juvenile idiopathic arthritis,
- enthesitis-related arthritis,
- ankylosing spondylitis,
- psoriatic arthritis,
- plaque 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 (TNF $\alpha$ ), which is involved in the immune (defence) system and present at increased levels in the inflammatory diseases listed above. By attaching to TNF $\alpha$ , 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 moderate to severe rheumatoid arthritis in adults. You may first be given other disease-modifying medicines, such as methotrexate. If you do not respond well enough to these medicines, you will be given Idacio.

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

Idacio can slow down the damage to the joints caused by the inflammatory disease and can help them move more freely.

Your doctor will decide if Idacio should be used with methotrexate or alone.

### Polyarticular juvenile idiopathic arthritis

Polyarticular juvenile idiopathic arthritis is an inflammatory disease of the joints.

Idacio is used to treat polyarticular juvenile idiopathic arthritis in patients from 2 years of age. You may first be given other disease-modifying medicines, such as methotrexate. If you do not respond well enough to these medicines, you will be given Idacio.

Your doctor will decide if Idacio should be used with methotrexate or alone.

### Enthesitis-related arthritis

Enthesitis-related arthritis is an inflammatory disease of the joints and the places where tendons join the bone.

Idacio is used to treat enthesitis-related arthritis in patients from 6 years of age. You may first be given other disease-modifying medicines, such as methotrexate. If you do not respond well enough to these medicines, you will be given Idacio.

### Ankylosing spondylitis

Ankylosing spondylitis is an inflammatory disease of the spine.

Idacio is used to treat ankylosing spondylitis. You may first be given other medicines. If you do not respond well enough to these medicines, you will be given Idacio.

### 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. You may first be given other medicines. If you do not respond well enough to these medicines, you will be given Idacio.

### Plaque psoriasis

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 chronic plaque psoriasis in adults and
- severe chronic plaque psoriasis in children and adolescents aged 4 to 17 years for whom topical therapy and phototherapies have either not worked very well or are not suitable.

### 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

- moderate to severe hidradenitis suppurativa in adults and
- moderate to severe hidradenitis suppurativa in adolescents aged 12 to 17 years

Idacio can reduce the number of nodules and abscesses caused by the disease and the pain that is often associated with the disease. You may first be given other medicines. If you do not respond well enough to these medicines, you will be given Idacio.

### Crohn's disease

Crohn's disease is an inflammatory disease of the digestive tract.

Idacio is used to treat

- moderate to severe Crohn's disease in adults and
- moderate to severe Crohn's disease in children and adolescents 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 in adults and children

Ulcerative colitis is an inflammatory disease of the large intestine.

Idacio is used to treat moderate to severe ulcerative colitis in adults and children aged 5 to 17 years. If you have ulcerative colitis you may 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

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.

You may first be given other medicines. If you do not respond well enough to these medicines, you will be given Idacio.

## **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 active tuberculosis or other severe infections (see “Warnings and precautions”). It is important that you tell your doctor if you have symptoms of infections, e.g. fever, wounds, feeling tired, dental problems.
- 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 an infection in one part of the body (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 you have problems with your lungs. These infections may be more serious and include tuberculosis, infections caused by viruses, fungi, parasites or bacteria, or other unusual infectious organisms and severe infection in the blood (sepsis).

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.

- Tell your doctor if you live or travel in regions where fungal infections (for example, histoplasmosis, coccidioidomycosis or blastomycosis) are very common.
- Tell your doctor if you have had infections which keep coming back or other conditions that increase the risk of infections.
- If you are over 65 years you may be more likely to get 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.

### Tuberculosis (TB)

- 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. If you have active tuberculosis, do not use Idacio.
- 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).

- Tuberculosis can develop during therapy even if you have had preventative treatment for tuberculosis.
- If symptoms of tuberculosis (for example cough that does not go away, weight loss, lack of energy, mild fever), or any other infection appear during or after therapy tell your doctor immediately.

### 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 cause the virus to become active again. In some rare cases, especially if you are taking other medicines that suppress the immune system, reactivation of HBV infection can be life-threatening.

### 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 may cause infections and should not be given while receiving Idacio. 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. Your doctor will decide if you should receive Idacio.

### 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 TNF $\alpha$  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 6-mercaptopurine. Tell your doctor if you are taking azathioprine or 6-mercaptopurine with Idacio.
- In addition, cases of non-melanoma 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 $\alpha$  blocker. If you have COPD, or are a heavy smoker, you should discuss with your doctor whether treatment with a TNF $\alpha$  blocker is appropriate for you.

## Autoimmune disease

- 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.

## **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. 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 on vaccines see the "Warnings and precautions" section).

### **Driving and using machines**

Idacio may have a small effect 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.

<b>Rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis</b>		
<b>Age or body weight</b>	<b>How much and how often to take?</b>	<b>Notes</b>
Adults	40 mg every other week	<p>In rheumatoid arthritis, methotrexate is continued while using Idacio. If your doctor decides that methotrexate is inappropriate, Idacio can be given alone.</p> <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.</p>

<b>Polyarticular juvenile idiopathic arthritis</b>		
<b>Age or body weight</b>	<b>How much and how often to take?</b>	<b>Notes</b>
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
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#### **Enthesitis-related arthritis**

<b>Age or body weight</b>	<b>How much and how often to take?</b>	<b>Notes</b>
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**

<b>Age or body weight</b>	<b>How much and how often to take?</b>	<b>Notes</b>
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.	If this dose does not work well enough, your doctor may increase the dosage to 40 mg every 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.  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**

<b>Age or body weight</b>	<b>How much and how often to take?</b>	<b>Notes</b>
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, 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. It is recommended that you use an antiseptic wash daily on the affected areas.
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<b>Crohn's disease</b>		
<b>Age or body weight</b>	<b>How much and how often to take?</b>	<b>Notes</b>
Children, adolescents and adults from 6 years of age weighing 40 kg or more	<p>Initial dose of 80 mg (as two 40 mg injections in one day), followed by 40 mg two weeks later.</p> <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.
Children and adolescents from 6 to 17 years of age weighing less than 40 kg	<p>Initial dose of 40 mg, followed by 20 mg two weeks later.</p> <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.

<b>Ulcerative colitis</b>		
<b>Age or body weight</b>	<b>How much and how often to take?</b>	<b>Notes</b>
Adults	<p>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 doctor may increase the dosage to 40 mg every week.
Children and adolescents from 5 to 17 years of age weighing 40 kg or more	<p>Initial dose of 160mg (as four 40mg injections in one day or two 40mg injections per day for two consecutive days), followed by 80mg (as two 40mg injections in one day) two weeks later.</p> <p>Thereafter, the usual dose is 80mg every other week or 40mg every week.</p>	You should continue taking Idacio at your usual dose, even after turning 18 years of age .
Children and adolescents from 5 to 17 years of age weighing less than 40 kg	<p>Initial dose of 80mg (as two 40mg injections in one day), followed by 40mg (as one 40mg injection) two weeks later.</p> <p>Thereafter, the usual dose is 40mg every other week or 20mg every week.</p>	You should continue taking Idacio at your usual dose, even after turning 18 years of age .

<b>Non-infectious uveitis</b>		
<b>Age or body weight</b>	<b>How much and how often to take?</b>	<b>Notes</b>
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.	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 of 20mg every other week. Idacio is recommended for use in combination with methotrexate.
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 of 40mg every other week. 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.

**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 physical activity 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 symptoms described above can be signs of the below listed side effects, which 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 (feeling of dizziness or sensation of room spinning);
- sensation of heart beating rapidly;
- high blood pressure;
- flushing;
- haematoma (collection of blood outside of blood vessels);
- 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 (swelling);
- fever;
- reduction in blood platelets which increases risk of bleeding or bruising;
- impaired healing.

**Uncommon** (may affect up to 1 in 100 people)

- opportunistic 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 (shaking);
- neuropathy (disorder of the nerves);
- stroke;
- 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 of the face);
- 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);
- cutaneous vasculitis (inflammation of blood vessels in the skin);
- Stevens-Johnson syndrome (early symptoms include malaise, fever, headache and 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 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 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 you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

## **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 pre-filled syringe in the outer carton in order to protect from light.

Alternative Storage:

When needed (for example when you are travelling), a single Idacio pre-filled syringe may be stored at room temperature (up to 30°C) for a maximum period of 14 days – be sure to protect it from light. Once removed from the refrigerator for room temperature storage, your pre-filled syringe **must be used within 14 days or discarded**, even if it is later returned to the refrigerator.

You should record the date when the syringe is first removed from refrigerator, and the date after which it should be discarded.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment

## **6. Contents of the pack and other information**

### **What Idacio contains**

- The active substance is adalimumab. Each pre-filled syringe contains 40 mg of adalimumab in 0.8 ml of solution.
- The other ingredients are sodium dihydrogen phosphate dihydrate, disodium phosphate dihydrate, mannitol, sodium chloride, citric acid monohydrate, sodium citrate, polysorbate 80, sodium hydroxide and water for injections.

### **What Idacio looks like and contents of the pack**

Idacio 40 mg solution for injection (injection) in pre-filled syringe is supplied as a sterile 0.8 ml clear, colourless solution of 40 mg adalimumab.

The Idacio pre-filled syringe is supplied in a glass syringe with needle guard and finger flanges. Each pack contains 2 or 6 pre-filled syringes, and 2 or 6 alcohol pads.

Idacio is available as a vial, a pre-filled syringe and as a pre-filled pen.

### **Marketing Authorisation Holder**

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### **This leaflet was last revised in**

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## **7. Instructions for use**

Be sure that you read, understand, and follow these Instructions for Use before injecting Idacio. Your healthcare provider should show you how to prepare and inject Idacio properly using the pre-filled syringe before you use it for the first time. Talk to your healthcare provider if you have any questions.



## 7. Instruction For Use

# Idacio<sup>®</sup>

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



**Note : images for illustration purposes only**

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

### **Important Information**

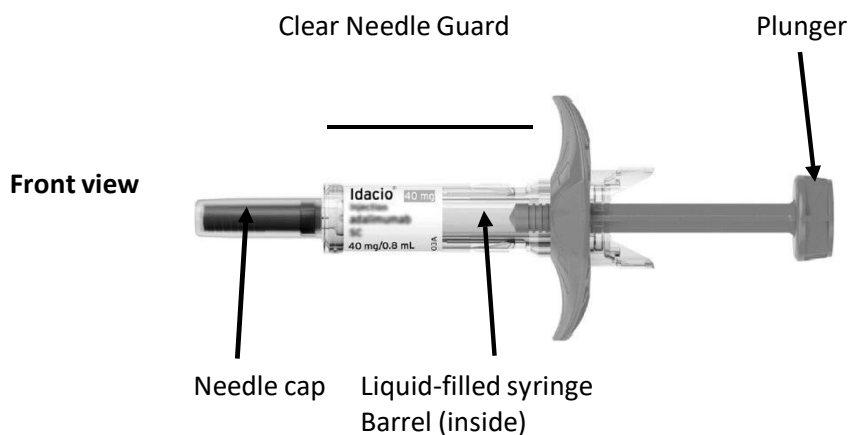
- Only use Idacio pre-filled syringe if your healthcare professional has trained you on how to use the pre-filled syringe correctly.
- Idacio is a pre-filled syringe for single use only.
- Idacio pre-filled syringe has a clear needle guard that covers the needle after the injection is complete.
- Children 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 the Idacio 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

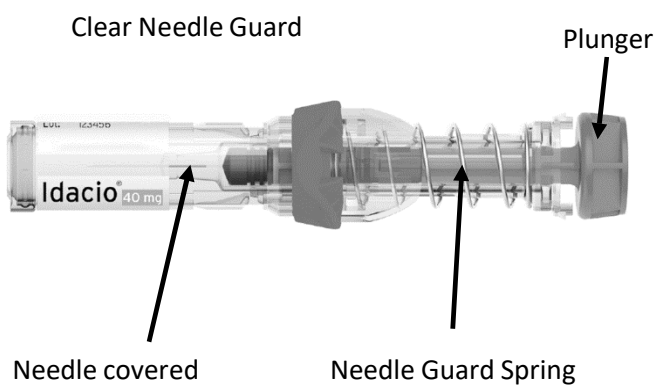
Before Use



Back view



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.

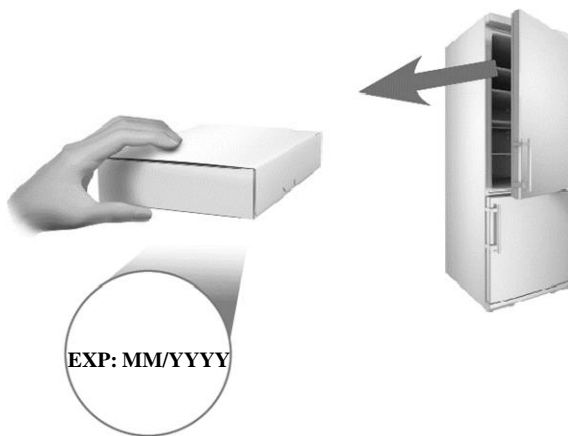


*Figure A*

**1.3** Remove the box from the refrigerator (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.



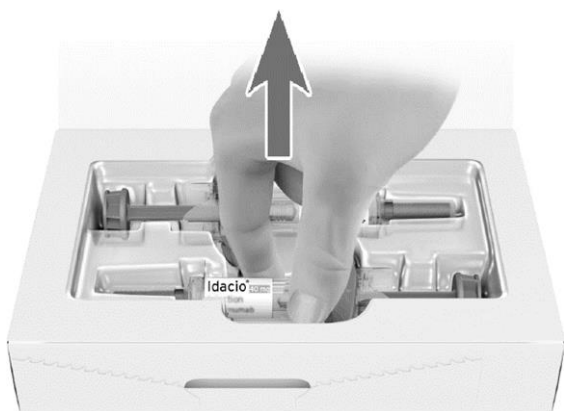
*Figure B*

**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:

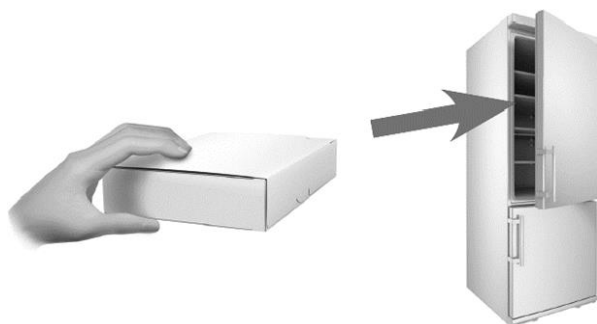
- place two fingers on middle of the clear needle guard
- pull the syringe straight up and out of the packaging (Figure C).

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(s).



*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).



*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.

## 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 Pre-filled 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).



*Figure G*

- The needle cap is securely attached (Figure H).



*Figure H*

- The needle guard spring is not extended (Figure I).

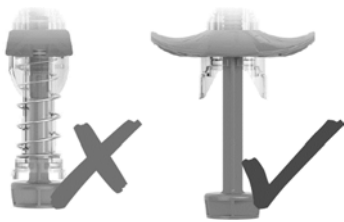


Figure I

**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 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).



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.

## 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).



Figure N

You may see drops of liquid at the needle tip.

- Throw away the needle cap.

**Warning: Do not** touch the needle.

### 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).





*Figure P*

- After the needle is inserted, release the pinched skin.

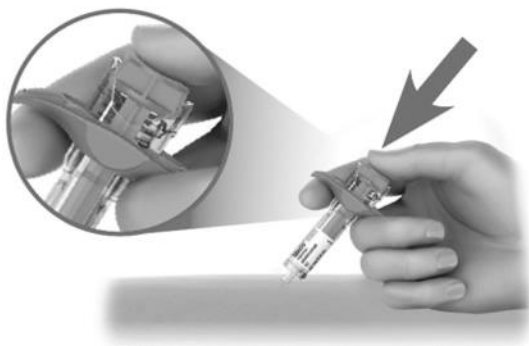
#### 6.4 Inject

- 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).



*Figure R*

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

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).



*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.

**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).



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.
- 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*