Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Idacio®

Solution for injection in a pre-filled pen

Active ingredient and its concentration: adalimumab 50 mg/ml

Each Idacio pre-filled pen contains: adalimumab 40 mg/0.8 ml

For the list of inactive ingredients and allergens - see section 6 "Additional information" in this leaflet.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness / for you. Do not pass it on to others. It may harm them, even if it seems to you that their illness / medical condition is similar to yours.

In addition to the leaflet, Idacio has a 'Patient safety information card'.

This card includes important safety information, which you should know and follow before starting treatment and during the treatment with Idacio. Review the 'Patient safety information card' and the patient leaflet before starting treatment with the medicine. Keep the card for further review if required.

Idacio is a biosimilar medicinal product. For further information regarding biosimilar products refer to the Israeli ministry of health website: https://www.health.gov.il/UnitsOffice/HD/MTI/Drugs/Registration/Pages/Biosimilars.as px

Please note that every time you get this medicine at the pharmacy, it is important that you check that you have been given the same medicine that your attending specialist has prescribed to you. If the medicine you have been given looks different from what you usually receive, or if the instructions for use have changed, please contact your pharmacist immediately to make sure you received the correct medicine. Only your attending specialist can switch your medicine or change the dosage of medicine containing adalimumab (the active ingredient in this medicine). Please check that the medicine that your specialist prescribed to you has the same brand name as the medicine you received from the pharmacist.

1. What is this medicine intended for?

Idacio is intended for the treatment of:

- Moderate to severe, active rheumatoid arthritis in adults, when other accepted treatment has been unsuccessful.
- Severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate.
- Severe active ankylosing spondylitis in adults, when other accepted treatment has been unsuccessful.
- Severe axial spondyloarthritis without radiographic evidence of ankylosing spondylitis in adults, when there was an inadequate response to, or intolerance to non-steroidal anti-inflammatory drugs (NSAIDs).
- Active and progressive psoriatic arthritis in adults, when other accepted treatment has been unsuccessful.
- Moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.
- Moderate to severe active Crohn's disease in adults, when other accepted treatment has either been unsuccessful or is inappropriate.
- Moderate to severe ulcerative colitis in adults, when other accepted treatment has been unsuccessful, or in patients who can't receive other accepted treatments.
- Moderate to severe, active hidradenitis suppurativa in adults, when accepted treatment has been unsuccessful.
- Intestinal Behcet's disease, when other accepted treatment has been unsuccessful.
- Uveitis – inflammation of the uvea (panuveitis, posterior or intermediate), from a non-infectious source, in adults, when treatment with steroids is inappropriate or inadequate.

Idacio contains the active ingredient adalimumab.
The active ingredient in Idacio, adalimumab, is a human monoclonal antibody.
Monoclonal antibodies are proteins that bind to specific targets.
The target of adalimumab is a protein called tumor necrosis factor (TNFα), which is involved in the immune (defence) system and is present at high levels in the inflammatory diseases listed above. By binding to TNFα, Idacio decreases the inflammatory process in these diseases.
Idacio is not intended for use in children and adolescents below the age of 18 years.

Therapeutic group: TNF blocker.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients in the medicine (see section 6 “Additional information”).
- You have active tuberculosis or other severe infections (see “Special warnings about using this medicine”). It is important that you inform your doctor if you have symptoms of infections, such as fever, wounds, feeling tired and dental problems.
- You have moderate or severe heart failure. It is important that you inform your doctor if you have or have had a serious heart problem (see “Special warnings about using this medicine”).

Special warnings about using this medicine
Before treatment with Idacio, inform your doctor if:

Allergic reactions

- If you experience 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 may be life-threatening.

Infections

- If you have an infection, including long-term infection or a local infection (for example, a leg ulcer), consult your doctor before using Idacio. If you are unsure, contact your doctor.
- You might develop infections more easily while you are receiving Idacio treatment. This risk may exacerbate if you have lung problems. These infections may be serious and include:
  - tuberculosis
  - infections caused by viruses, fungi, parasites or bacteria
  - severe infections in the blood (sepsis)

  In rare cases, these infections may be life-threatening. It is important to tell your doctor if you experience symptoms such as fever, wounds, feeling tired or dental problems. Your doctor may recommend you to stop treatment with Idacio temporarily.
- Consult your doctor if you live or travel in regions where fungal infections such as histoplasmosis, coccidioidomycosis or blastomycosis, are very common.
- Consult your doctor if you have had recurrent infections or other conditions that increase the risk of infections.
- If you are over 65 years of age, you may be more susceptible to infections during treatment with Idacio. Your doctor and you should pay special attention to signs of infection while you are being treated with Idacio. It is important to tell your doctor if you experience symptoms of infections such as fever, wounds, feeling tired or dental problems.

Tuberculosis

- 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 Idacio, your doctor will check you for signs and symptoms of tuberculosis before starting Idacio treatment. This will include a comprehensive medical evaluation including your medical history and appropriate diagnostic tests (for example, chest X-ray and a test for tuberculosis detection). The conduct and results of these tests should be recorded in your '**Patient safety information card**'.
- Tuberculosis may develop during the treatment even if you have received prophylactic treatment against tuberculosis.
- Contact your doctor immediately if symptoms of tuberculosis (such as persistent cough, weight loss, lack of energy, low-grade fever) or of any other infection appear during or after treatment with Idacio.

Hepatitis B

- Tell your doctor if you are a carrier of the hepatitis B virus (HBV), if you have active hepatitis B or if you think that you are at risk of contracting hepatitis B.
- Your doctor should perform tests for HBV. In people who are HBV carriers, Idacio may cause HBV reactivation.
- In rare cases, especially if you are taking other medicines that suppress the immune system, reactivation of HBV can be life-threatening

Dental procedure or surgery

- If you are about to undergo dental procedures or surgery, inform your doctor that you are taking Idacio. Your doctor may recommend temporary discontinuation of Idacio.

Demyelinating diseases

- If you have or develop a 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 experience symptoms like changes in vision, weakness in the arms or legs or numbness or tingling in any part of the body.

Vaccinations

- Certain vaccines may cause infections and should not be received during Idacio treatment.
- Consult your doctor before you receive any vaccine.
- If you have been treated with Idacio during pregnancy, your baby may be at a higher risk of developing an infection for approximately five months after the last dose you received during pregnancy. It is important that you tell your baby's doctors and health care professionals that you have been treated with Idacio

during pregnancy, so they can decide when your baby can receive vaccines.

Heart failure

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

Fever, bruising, bleeding or pallor

- In certain patients, the body fails to produce a sufficient amount of blood cells that fight infections or help to stop bleeding. Your doctor may decide to stop treatment. If you develop a fever that does not resolve, mild bruises or if you bleed very easily, or look very pale, contact your doctor immediately.

Cancer

- Very rare cases of certain types of cancer have been described in adults and children treated with adalimumab or other TNF blockers.
- People with more severe rheumatoid arthritis suffering from the disease for a long time may have a higher than average risk of developing lymphoma (a cancer that affects the lymph system) and leukemia (a cancer that affects the bone marrow and blood).
- If you are treated with Idacio, the risk of developing lymphoma, leukemia, or other type of cancer may increase. On rare occasions, a rare and severe type of lymphoma has been observed in patients taking adalimumab. Some of those patients were also treated with azathioprine or 6-mercaptopurine.
- Tell your doctor if you are taking azathioprine or 6-mercaptopurine together with Idacio.
- 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, tell your doctor.
- Cases of cancers other than lymphoma have been reported in patients with a specific type of lung disease called chronic obstructive pulmonary disease (COPD) taking another TNF blocker. If you have chronic obstructive pulmonary disease, or if you are a heavy smoker, consult your doctor whether treatment with a TNF blocker is appropriate for you.

Autoimmune disease

- On rare occasions, treatment with Idacio may cause lupus-like syndrome. Contact your doctor if symptoms such as persistent unexplained rash, fever, joint pain or tiredness occur.

Smoking
If you are a heavy smoker, you should consult your attending doctor as to whether treatment with a TNF blocker is appropriate for you (for further information, see section “Special warnings about using this medicine”).

Children and adolescents
Idacio is not intended for use in children and adolescents below the age of 18 years.

Drug interactions
If you are taking or have recently taken, other medicines including nonprescription medications and dietary supplements, tell your doctor or pharmacist.
Do not take Idacio with medicines containing the following active ingredients due to increased risk of serious infections:
- anakinra
- abatacept

These medicines are used for the treatment of rheumatoid arthritis.
Idacio can be taken together with:
- methotrexate
- certain disease-modifying anti-rheumatic agents for treatment of arthritis (such as sulfasalazine, hydroxychloroquine, leflunomide and injectable gold preparations)
- steroids or analgesics, including non-steroidal anti-inflammatory drugs (NSAIDs)

If you have questions, ask your doctor.

Pregnancy and breastfeeding
- You should consider the use of adequate contraceptives to prevent pregnancy and continue using them for at least 5 months after the last Idacio treatment.
- If you are pregnant, think you may be pregnant or are planning to become pregnant, consult your doctor regarding taking this medicine.
- Idacio should only be used during a pregnancy if needed.
- According to a study examining use in pregnant women, no higher risk of birth defects was observed when the mother had received adalimumab during pregnancy compared to mothers with the same disease who did not receive adalimumab.
- Idacio can be taken while breastfeeding.
- If you received Idacio during pregnancy, your baby may have an increased risk of developing an infection.
- It is important to inform your baby’s doctor and health care professionals in the clinic and in the Family Health Center (Tipat-Halav) that you have been taking Idacio during pregnancy, before your baby receives any

vaccine. For more information on vaccines, see section “Special warnings about using this medicine”.

Driving and using machines

Idacio may have a minor effect on the ability to drive, cycle or operate machines. After treatment with Idacio, sensation of dizziness and vision disturbances may occur.

Important information about some of this medicine’s ingredients

This medicine contains less than 1 mmol sodium (23 mg) per 0.8 ml dose, therefore it is considered sodium free.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions.
Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.
Do not exceed the recommended dose.

Method of administration

Idacio in a pre-filled pen is injected under the skin (subcutaneous administration).
Detailed instructions on how to inject Idacio are provided in section 7 "Instructions for use".

If you have accidentally taken a higher dosage

If you accidentally inject Idacio more frequently than instructed by your doctor or pharmacist, call your doctor or pharmacist and tell them about it. Always bring the medicine package with you, even if it is empty.

If you forgot to inject Idacio

If you forgot to inject Idacio, inject the next dose as soon as you remember. Subsequently inject as originally scheduled, had you not forgotten a dose.
Adhere to the treatment as recommended by your doctor.
Even if your health improves, do not stop treatment with the medicine without consulting your doctor.

If you stop taking Idacio

Idacio discontinuation should be discussed with your doctor. Your symptoms may return upon Idacio discontinuation.

Do not take medicines in the dark! Check the label and dose every time you take a medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Idacio may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.
Most side effects are mild to moderate. However, some of the side effects may be serious and require treatment.
Side effects may occur at least up to 4 months after the last Idacio treatment.

Contact your doctor immediately if you notice one of the following symptoms:

- severe rash, hives or other signs of allergic reaction
- swelling of the face, hands, feet
- difficulty breathing, difficulty swallowing
- shortness of breath upon physical activity or lying down or swelling of the feet

Contact your doctor as soon as possible if you notice one of the following symptoms:

- signs indicating infection, such as fever, nausea, wounds, dental problems, burning on urination
- feeling weak or tired
- cough
- tingling
- numbness
- double vision
- arm or leg weakness
- a bruise or an open sore that does not heal
- signs and symptoms indicating blood system disorders such as persistent fever, bruising, bleeding and paleness

The symptoms described above can be signs of the side effects listed below, which have been observed with adalimumab.

Very common side effects (effects that occur in more than one in ten users):

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

Common side effects (effects that occur in 1-10 out of 100 users):

- serious infections (including sepsis and influenza)
- intestinal infections (including gastroenteritis)
- skin infections (including cellulitis, herpes zoster)
- ear infections
- oral infections (including tooth infections and cold sores)
- reproductive system infections
- urinary tract infection
- fungal infections
- joint infections
- benign tumors
- skin cancer
- allergic reactions (including seasonal allergy)
- dehydration
- mood swings (including depression)
- anxiety
- difficulty sleeping
- sensation disorders such as sensation of tingling, prickling or numbness
- migraine
- nerve root compression (including low back pain and leg pain)
- vision disturbances
- eye inflammation
- eyelid inflammation and eye swelling
- vertigo (sensation of dizziness)
- sensation of rapid heartbeats
- high blood pressure
- flushing
- hematoma (accumulation of blood outside of blood vessels)
- cough
- asthma
- shortness of breath
- gastrointestinal bleeding
- dyspepsia (indigestion, bloating, heartburn)
- acid reflux disease
- sicca syndrome (including dry eyes and dry mouth)
- itching
- itchy rash
- bruises
- 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 the number of platelets, which increases the risk of bleeding or bruising
- impaired healing

Uncommon side effects (effects that occur in 1-10 out of 1,000 users):

- opportunistic infections (including tuberculosis and other infections that occur when body resistance to diseases is reduced)
- nervous system infections (including viral meningitis)
- eye infections
- bacterial infections
- diverticulitis (infection and inflammation of the colon)
- cancer
- cancer affecting the lymph system
- melanoma
- immune disorders that may affect the lungs, skin and lymph nodes (most commonly presenting as sarcoidosis)
- inflammation of the blood vessels (vasculitis)
- tremor
- peripheral nerve disease (neuropathy)
- stroke
- hearing loss, buzzing
- sensation of irregular heartbeats such as skipped beats
- heart problems that may cause shortness of breath or ankle swelling
- heart attack
- formation of a sac in the wall of a major artery, inflammation and clot in a vein, blockage of a blood vessel
- lung diseases causing shortness of breath (including inflammation)
- pulmonary embolism (blockage of a lung artery)
- abnormal accumulation of fluid in the pleural space (pleural effusion)
- inflammation of the pancreas which causes severe pain in the abdomen and back
- difficulty swallowing
- facial oedema (swelling of the face)
- gallbladder inflammation, gallbladder stones

- fatty liver
- night sweats
- scarring
- muscle tissue breakdown
- systemic lupus erythematosus (including inflammation of skin, heart, lung, joints and other organs)
- sleep disturbances
- impotence
- inflammations

Rare side effects (effects that occur in 1-10 out of 10,000 users):

- leukemia (cancer affecting the blood and bone marrow)
- acute allergic reaction with shock
- multiple sclerosis
- nerve disorders (such as optic nerve inflammation and Guillain-Barré syndrome that may cause muscle weakness, sensory impairment, sensation of tingling in the arms and upper body)
- heart beating stops
- scarring of the lung
- intestinal perforation (hole in the intestine)
- hepatitis
- reactivation of hepatitis B virus
- autoimmune hepatitis (inflammation of the liver caused by the body's immune system)
- inflammation of blood vessels in the skin (cutaneous vasculitis)
- Stevens-Johnson syndrome (early symptoms include malaise, fever, headache and rash)
- facial oedema (swelling of the face) as an allergic reaction
- erythema multiforme (inflammatory skin rash)
- lupus-like syndrome
- angioedema (localized swelling of the skin)
- lichenoid skin reaction (itchy reddish-purple skin rash)

Side effects of unknown frequency (the frequency cannot be estimated from the 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 herpesvirus-8. Kaposi's sarcoma most commonly appears as purple lesions on the skin
- liver failure
- worsening of dermatomyositis (seen as a skin rash accompanied by muscle weakness)
- Weight gain (For most patients, the weight gain was small).

Some side effects observed with the use of the preparation have no symptoms and may only be discovered by blood tests, among them:
Very common side effects (effects that occur in more than one in ten users):

- low levels of white blood cells
- low levels of red blood cells
- increase in blood lipids
- increase in liver enzymes

Common side effects (effects that occur in 1-10 out of 100 users):

- high levels of white blood cells
- low levels of platelets
- increased uric acid in the blood
- abnormal blood levels of sodium
- low blood levels of calcium
- low blood levels of phosphate
- high blood sugar
- high blood levels of lactate dehydrogenase enzyme
- presence of autoantibodies in the blood
- low blood levels of potassium

Uncommon side effects (effects that occur in 1-10 out of 1,000 users):

- high bilirubin values (blood test for liver function)

Rare side effects (effects that occur in 1-10 out of 10,000 users):

- low levels of white blood cells, red blood cells and platelets

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link:
https://sideeffects.health.gov.il
In addition, you can report by sending an email to the registration holder's patient safety unit: drugsafety@neopharmgroup.com

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by the doctor.

- Do not use the medicine after the expiry date (exp. date) appearing on the outer and inner packages and on the pen. The expiry date refers to the last day of that month.

Storage conditions:

- Store in a refrigerator: 2°C-8°C (this temperature range is predominant in most household refrigerators).
- Do not freeze.
- Keep the pen in the outer carton package in order to protect from light.

Alternative storage conditions:

- When needed (for example, when you are traveling), a **single** pre-filled pen may be stored at a temperature below 25°C for a maximal period of 28 days – protect the pen from light.
- Once the syringe is taken out of the refrigerator and is stored at a temperature below 25°C, **the pen must be used within 28 days or discarded**, even if it is returned to the refrigerator.
- You should record the date on which the syringe was first taken out of the refrigerator and the date after which it should be discarded.
- Do not throw away any medicines via wastewater or household waste. Ask your doctor or pharmacist how to dispose of medicines you no longer need. These measures will help protect the environment.

6. Additional information

- In addition to the active ingredient, the medicine also contains: Mannitol, sodium chloride, disodium phosphate dihydrate, citric acid monohydrate, polysorbate 80, sodium dihydrogen phosphate dihydrate, sodium citrate, sodium hydroxide and water for injections.

- What the medicine looks like and contents of the pack:

The package contains Idacio solution for injection in a pre-filled pen. The solution is a sterile solution of 40 mg adalimumab in a volume of 0.8 ml.

The pen is intended for single use and contains a pre-filled syringe containing a clear colorless solution of adalimumab 40 mg/0.8 ml. The prefilled pen is supplied in the following packs:

Idacio 40 mg solution for injection:

- 2 pre-filled pens (0.8 ml sterile solution), with 2 alcohol pads.
- 6 pre-filled pens (0.8 ml sterile solution), with 6 alcohol pads.

Not all pack sizes or formulations may be marketed.

Registration holder's name and address: Neopharm (Israel) 1996 Ltd., 6 Hashiloach St. POB 7063, Petach Tikva 4951439

Manufacturer's name and address: Fresenius Kabi Austria GmbH, Hafnerstrasse 36, 8055 Graz, Austria

Registration number of the medicine in the National Drug Registry of the Ministry of Health:165-83-36283

This leaflet was revised in August 2022 according to MOH guidelines.

7. Instructions for use

Read carefully all the instructions before using Idacio pre-filled pen.

Important Information:

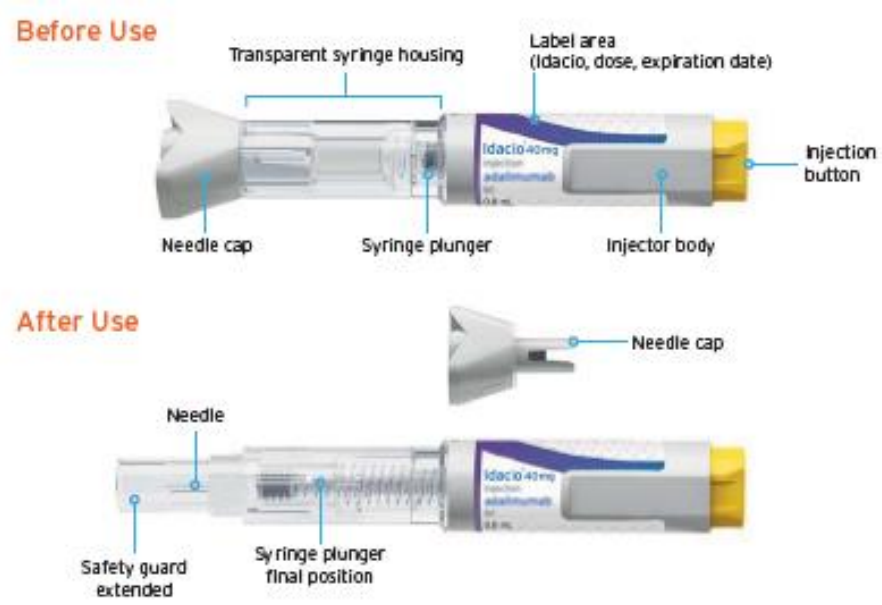
Use Idacio pre-filled pen only if your doctor or nurse have instructed you how to use it correctly.

- Idacio pre-filled pen is intended for single use only. The pre-filled pen contains the full dose of adalimumab.
- Always inject using the technique your doctor or nurse taught you.
- Keep the pre-filled pen out of the reach and sight of children.
- Do not insert your fingers into the opening of the safety guard.
- Do not use the Idacio pre-filled pen if it has been frozen or left in direct sunlight.
- Consult your doctor or nurse if you have further questions or concerns.

Storage instructions:

- Store the pre-filled pen in its original carton package to protect from light.
- Store the pre-filled pen in a refrigerator between 2^{o}C to 8^{o}C.
- If needed, for example when traveling, a single pre-filled pen can be stored at room temperature for up to 28 days.

Idacio pre-filled pen:



Step 1 - Prepare for injection

Each pack of Idacio pre-filled pen contains 2 or 6 pre-filled pens.

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

1.2 You will also need (Figure A):

- an alcohol pad (included in the pack)
- a cotton ball or gauze pad
- a sharps disposal container

Figure A

1.3 Take the pack out of the refrigerator (Figure B).

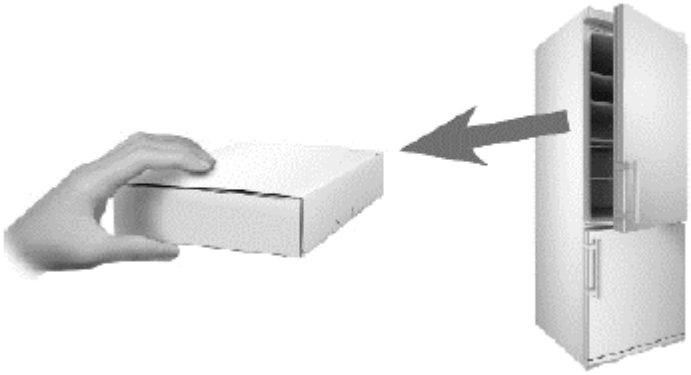


Figure B

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

Figure C

Warning: Do not use the medicinal product if the expiration date has passed.

1.5 Take the pre-filled pen out of the original pack:

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

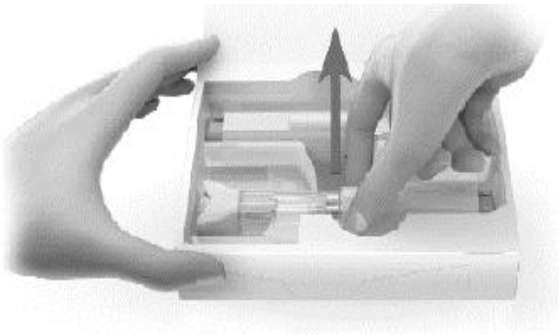


Figure D

Place the pen on a clean flat surface.

1.6 Place the remaining pre-filled pens in their original pack back in the refrigerator (Figure E).

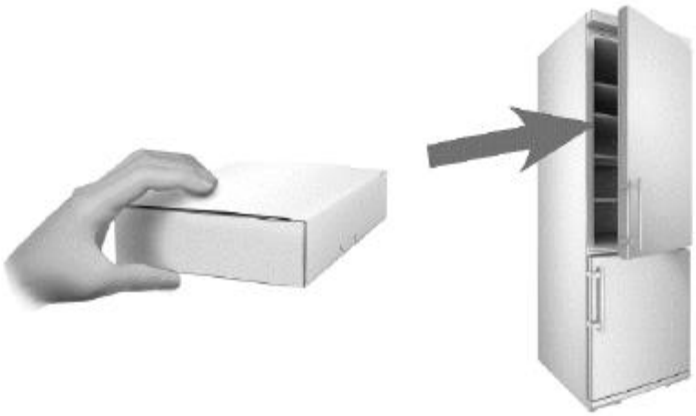


Figure E

Read the section "How to store the medicine?" on how to store your unused pre-filled pens.

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

Figure F

Injecting cold medicine may be painful.

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

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

Step 2 - Wash your hands

2.1 Wash your hands thoroughly with soap and water (Figure G) and dry them.

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

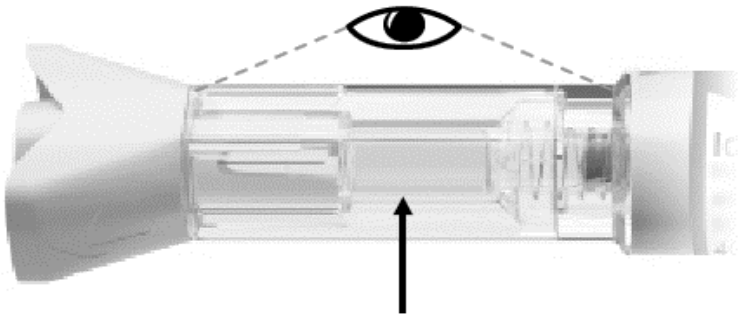
Figure G

Step 3 - Check the pre-filled pen

3.1 Check the transparent syringe housing to make sure that:

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

- The glass syringe is not cracked or broken (Figure H).



Transparent syringe housing

Figure H

Warning: Do not use the pre-filled pen if you notice that the liquid contains particles, or if the liquid is cloudy or discolored, or contains flakes or if you notice any other sign of damage. If you notice any of these signs, discard the pen into the sharps disposal container and consult your doctor or pharmacist.

3.2 Check the label to make sure that:

- Make sure that the name indicated on the pre-filled pen is Idacio (Figure I).

- Make sure that the expiration date indicated on the syringe has not passed (Figure I).

Figure I

Warning: Do not use the pre-filled pen if the name indicated on the label is not Idacio and/or if the expiration date indicated on the label has passed. If so, discard the pen into the sharps disposal container and consult your doctor or pharmacist.

Step 4 - Choose the injection site

4.1 Choose the injection site (Figure J) on:

- Top of the thighs

- Abdomen (at least 5 centimeters away from the navel)

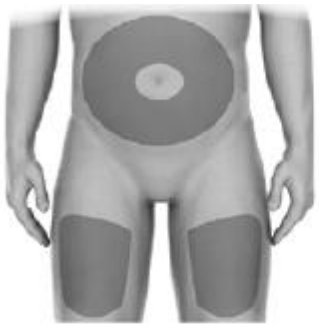


Figure J

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

Warning: Do not inject into an area that is painful or tender to touch, bruised, red, hard to touch, scarred or with stretch marks.

Warning: If you have psoriasis, do not inject into areas of red, thick lesions or areas with raised or peeling skin.

Step 5 - Clean the injection site

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

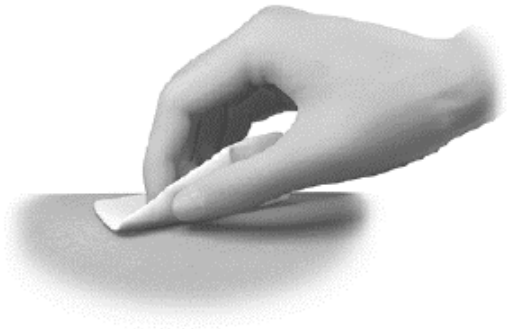


Figure K

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

Step 6 - Perform the injection

6.1 Remove the needle cap.

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

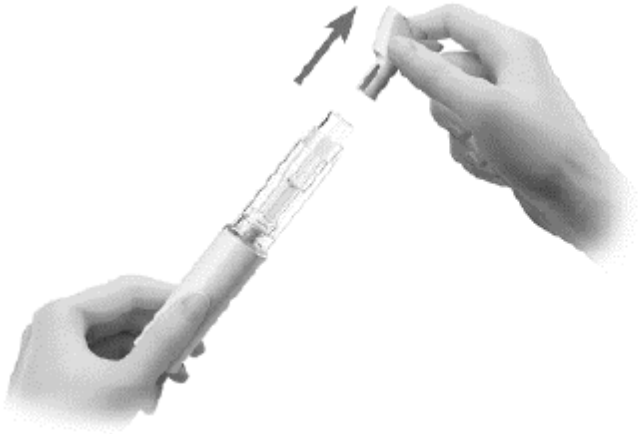


Figure L

You may see drops of liquid at the needle tip.

- Discard the needle cap.

Warning: Do not twist the cap.

Warning: Do not recap the pre-filled pen.

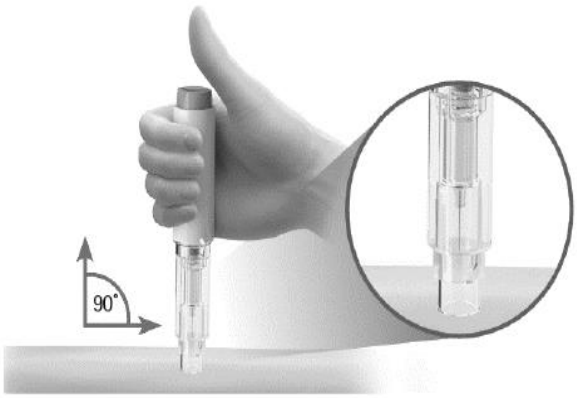
6.2 Position the pre-filled pen.

- Hold the pre-filled pen so that you can see the transparent syringe housing.

- Place your thumb above the yellow injection button. Do not touch the injection button. (Figure M).

Figure M

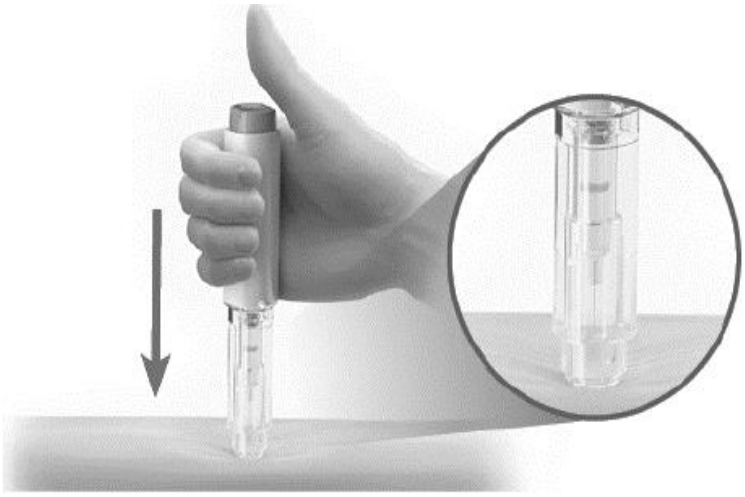
- Hold the pre-filled pen against the skin at a 90° angle (Figure N).



Before injection

Figure N

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



Before injection

Figure O

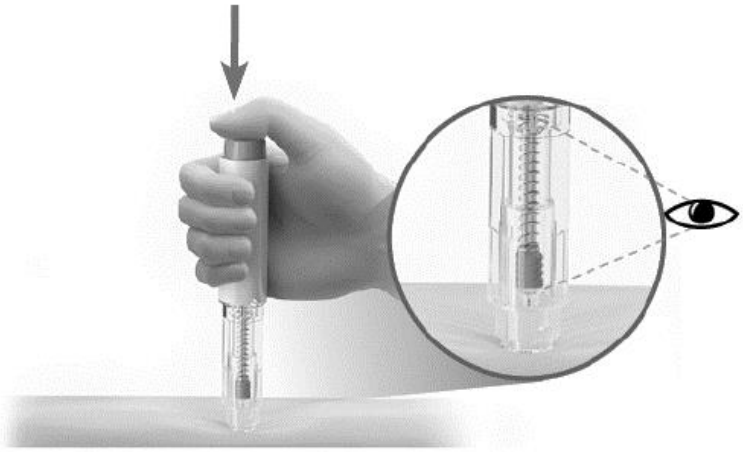
6.3 Administer the injection.

- Push the injection button (Figure P).

- You will hear a loud click, which means the injection has started.

- Continue to **hold** the pen firmly.

- **Visually follow** the syringe plunger to make sure it moves all the way down to the bottom (Figure P).



After injection

Figure P

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

- When the syringe plunger has moved to the bottom and has stopped moving, continue holding the pen for 5 more seconds.

- Then lift the pre-filled pen from your skin (Figure Q). The safety guard will slide down and lock into place to protect you from the needle (Figure Q).

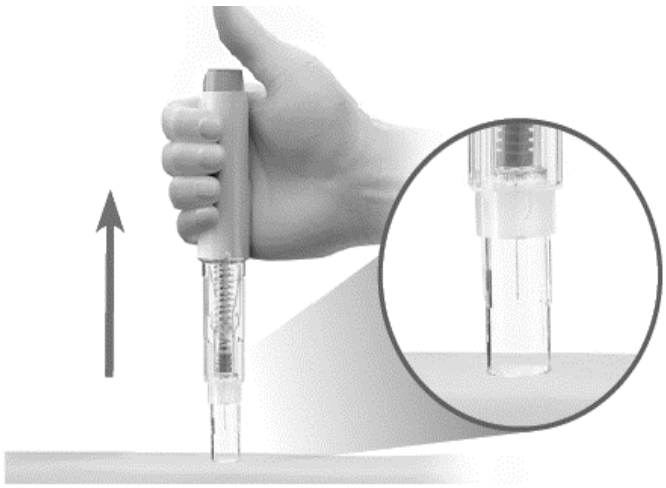


Figure Q

Warning: In case of any problem, consult your doctor or pharmacist.

6.4 If you notice blood or liquid on the skin, gently press a cotton ball or gauze pad on the injection site (Figure R).

Figure R

Step 7 - Discard the pen

7.1 Discard the used pre-filled pen into a sharps disposal container immediately after use as instructed by your doctor, nurse or pharmacist.

(Figure S).

Figure S

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

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

Step 8 - Record the injection

You should keep a record when and where to perform the next injection. Therefore, record the dates and sites which you have already used for your injections (Figure T).

Figure T