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

This medicine is dispensed with a doctor's prescription only

Hyrimoz®

Solution for injection in pre-filled syringe
Solution for subcutaneous injection

Name and quantity of active ingredient:
Each prefilled syringe of Hyrimoz 20 mg contains adalimumab 20 mg in 0.4 ml (50 mg/ml)
Each prefilled syringe of Hyrimoz 40 mg contains adalimumab 40 mg in 0.8 ml (50 mg/ml)

For a list of inactive ingredients see section 2 under 'Important information about some of the ingredients of Hyrimoz', and section 6.

Read the entire leaflet carefully before you start using this medicine.
- This leaflet contains concise information about Hyrimoz. If you have any further questions, consult your doctor or pharmacist.
- This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

Please note
It is important that, every time you get this medicine at the pharmacy, you check that you have been given the same medicine that your specialist prescribed you.
If the medicine you are given looks different from what you usually get, or if the instructions for use have changed, please consult your pharmacist immediately to make sure you received the correct medicine. Only your specialist can switch your medicine or change the dosage of a medicine that contains adalimumab.
Please check that the medicine that your specialist prescribed you has the same brand name as the medicine you got from the pharmacist.
Hyrimoz is a biosimilar preparation. For more information about biosimilar preparations, visit the Ministry of Health website:
https://www.health.gov.il/UnitsOffice/HD/MTI/Drugs/Registration/Pages/Biosimilars.aspx

In addition to the patient leaflet, Hyrimoz also has a Patient Safety Information Card. This card contains important safety information that you need to know and that you should follow before you start and during treatment with Hyrimoz. Carefully read the Patient Safety Information Card and patient leaflet before using this medicine. Keep the card in case you need to read it again.

1. What is Hyrimoz intended for?

Rheumatoid arthritis
Hyrimoz in combination with methotrexate is indicated for:
- treatment of moderate to severe, active rheumatoid arthritis in adults when the response to disease-modifying anti-rheumatic drugs (DMARDs) including methotrexate has been inadequate.
- treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate.
  Hyrimoz can be given as monotherapy in cases of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate.
  Hyrimoz has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function, when given in combination with methotrexate.

Polyarticular juvenile idiopathic arthritis
- Hyrimoz in combination with methotrexate is indicated for the treatment of active polyarticular juvenile idiopathic arthritis, in patients from the age of 2 years who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs). Hyrimoz can be given as monotherapy in cases of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. Adalimumab has not been studied in patients aged less than 2 years.

Enthesitis-related arthritis
- Hyrimoz is indicated for the treatment of active enthesitis-related arthritis in patients, 6 years of age and older, who have had an inadequate response to, or who are intolerant of, conventional therapy.

Ankylosing spondylitis (AS)
- Hyrimoz is indicated for treatment of adults with severe active ankylosing spondylitis who have had an inadequate response to conventional therapy.

Axial spondyloarthritis without radiographic evidence of AS
- Hyrimoz is indicated for the treatment of adults with severe axial spondyloarthritis without radiographic evidence of the disease, but with signs of inflammation by radiological and/or laboratory tests including MRI and/or CRP levels, who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs (NSAIDs).

Psoriatic arthritis
- Hyrimoz is indicated for the treatment of active and progressive psoriatic arthritis in adults when the response to previous DMARD therapy has been inadequate. Hyrimoz has been shown to reduce the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease and to improve physical function.

Psoriasis
- Hyrimoz is indicated for the treatment of moderate to severe chronic plaque psoriasis in adults who are candidates for systemic therapy.

Paediatric plaque psoriasis
- Hyrimoz is indicated for the treatment of severe chronic plaque psoriasis in children and adolescents from 4 years of age who have had an inadequate response to or are inappropriate candidates for topical therapy and phototherapy.

Hidradenitis suppurativa (HS)
- Hyrimoz is indicated for the treatment of active moderate to severe hidradenitis suppurativa in adults and adolescents from 12 years of age who have had an inadequate response to systemic conventional hidradenitis suppurativa therapy.

Crohn's disease
- Hyrimoz is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in adults with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy. Hyrimoz is indicated for reducing signs and symptoms and inducing clinical remission in these patients even when they have lost response to or are intolerant of medicine that contains infliximab.

Paediatric Crohn's disease
- Hyrimoz is indicated for the treatment of moderately to severely active Crohn's disease in children from 6 years of age who have had an inadequate response to conventional therapy including primary nutrition therapy and corticosteroid therapy, and/or immunomodulators (which modify the immune system), or who are intolerant to or have contraindications for conventional therapy.

Ulcerative colitis
- Hyrimoz is indicated for treatment of moderately to severely active ulcerative colitis in adults who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have contraindications for conventional therapy.

Paediatric ulcerative colitis
- Hyrimoz is indicated for the treatment of moderately to severely active ulcerative colitis in children from 6 years of age who have had an inadequate response to conventional therapy including corticosteroids and/or 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have contraindications for conventional therapy.

Uveitis
- Hyrimoz is indicated for the treatment of non-infectious (pan, posterior, or intermediate) uveitis in adults who have had an inadequate response to corticosteroid therapy, in patients in need of corticosteroid-sparing, or in whom corticosteroid treatment is inappropriate.

Paediatric uveitis
- Hyrimoz is indicated for the treatment of chronic non-infectious uveitis in children from 2 years of age who have had an inadequate response to conventional therapy, or are intolerant to conventional therapy, or in whom conventional therapy is inappropriate.

Intestinal Behcet's disease
- Hyrimoz is indicated for the treatment of intestinal Behcet's disease in patients who have had an inadequate response to conventional therapy.

Hyrimoz contains the active substance adalimumab. Adalimumab is a human monoclonal antibody. Monoclonal antibodies are proteins that bind to certain targets. Adalimumab's target is a protein known as tumor necrosis factor (TNFα), which is involved in the immune (defense) system and is found at high levels in the inflammatory diseases listed above. By binding to TNFα, Hyrimoz reduces the inflammatory process in these diseases.

There is no information about use of Hyrimoz in children below the age of two.

Therapeutic group:
TNFα blocker.

2. Before using Hyrimoz

Do not use Hyrimoz if:
- you are allergic (hypersensitive) to the active ingredient adalimumab or to any of the other ingredients in Hyrimoz (see also section 6 'Additional Information').
- you have a severe infection, including tuberculosis, blood poisoning (sepsis) or other opportunistic infections (unusual infections associated with a weakened immune system). It is important that you tell your doctor if you have symptoms of infections, such as fever, wounds, feeling tired, and dental problems (see also under 'Special warnings about using Hyrimoz').
- you have moderate or severe heart failure. It is important that you tell your doctor if you have had or have a serious heart condition (see also under 'Special warnings about using Hyrimoz').

Special warnings about using Hyrimoz
Inform your doctor before treatment with Hyrimoz:
Allergic reaction
- If you have allergic reactions with symptoms such as chest tightness, wheezing, dizziness, swelling or rash, stop taking Hyrimoz and contact your doctor immediately, since in rare cases, these reactions can be life-threatening.

Infections
- If you have an infection, including long-term or localized infection (for example a leg ulcer), consult your doctor before starting Hyrimoz. If you are unsure, contact your doctor.
- You might get infections more easily while you are receiving Hyrimoz treatment. This risk may increase if your lung function is reduced. These infections may be more serious and include tuberculosis, infections caused by viruses, fungi, parasites or bacteria, or other unusual infectious organisms and blood poisoning (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 decide to temporarily stop your Hyrimoz treatment.

Tuberculosis
- 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 Hyrimoz. This will include a thorough medical evaluation including your medical history and suitable screening tests (for example chest X-ray and a tuberculin test for tuberculosis). The conduct and results of these tests will be recorded **on your Patient Safety Information Card**. It is very important that you tell your doctor if you have ever had tuberculosis, or if you have been in close contact with someone who has tuberculosis. If you have active tuberculosis, do not use Hyrimoz. Tuberculosis can develop during therapy even if you have had preventative treatment. If symptoms of tuberculosis (persistent cough, weight loss, listlessness, mild fever) or any other infection appears during or after therapy tell your doctor immediately.

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

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

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

Surgery or dental procedure
- If you are about to have surgery or a dental procedure, tell your doctor that you are taking Hyrimoz. Your doctor may recommend temporarily stopping Hyrimoz.

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 Hyrimoz. 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.

Vaccines
- Certain vaccines contain living but weakened forms of disease-causing bacteria or viruses and must not be given during treatment with Hyrimoz. Check with your doctor before you receive any vaccines. If possible, children should be given all routine vaccinations that are scheduled for their age before beginning treatment with Hyrimoz. If you receive Hyrimoz while you are pregnant, your baby may be at higher risk of getting an infection for up to about 5 months after the last dose you received during pregnancy. It is important that you tell your baby's doctor and other health care professionals about your Hyrimoz 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 Hyrimoz, your heart failure status must be closely monitored by your doctor. If you develop new or worsening symptoms of heart failure (such as shortness of breath, or swelling of your feet), you must contact your doctor immediately.

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

Cancer
- There have been very rare cases of certain kinds of cancer in children and adults taking adalimumab or other TNFα blockers. Patients 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 leukemia (cancers that affect blood cells and bone marrow). If you take Hyrimoz, the risk of getting lymphoma, leukemia, or other cancers may increase. On rare occasions, a specific and severe type of lymphoma has been observed in patients taking adalimumab. Some of those patients were also treated with the medicines azathioprine or mercaptopurine. Tell your doctor if you are taking azathioprine or mercaptopurine with Hyrimoz.
- Cases of non-melanoma skin cancer have been observed in patients taking adalimumab. If new areas of damaged skin appear during or after treatment with Hyrimoz or if existing areas of damage change appearance, tell your doctor.
- There have been cases of cancers other than lymphoma in patients with a specific type of lung disease called chronic obstructive pulmonary disease (COPD) treated with another TNFα blocker. If you have COPD, or if you are a heavy smoker, you should discuss with your doctor whether treatment with a TNFα blocker is appropriate for you.

Autoimmune disease
- On rare occasions, treatment with Hyrimoz could result in 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, discuss with your doctor whether treatment with a TNFα blocker is appropriate for you.

Children and adolescents
Vaccinations: if possible, children should receive all of the necessary vaccinations before starting treatment with Hyrimoz.
- Do not use the prefilled syringe that contains 40 mg of the active substance adalimumab if a different dosage than 40 mg was recommended.

Interactions with other medicines
If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.

Do not take Hyrimoz with medicines containing the active substances anakinra or abatacept, used to treat rheumatoid arthritis, due to increased risk of serious infection.

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

If you have any questions, ask your doctor.

Pregnancy and breastfeeding
Pregnancy -
- You should consider the use of adequate contraception to prevent pregnancy and continue its use for at least 5 months after the last Hyrimoz treatment.
- If you are pregnant, think you may be pregnant, or are planning to have a baby, ask your doctor for advice before taking Hyrimoz.
- Hyrimoz 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.
- If you receive Hyrimoz during your pregnancy, your baby may have a higher risk of getting an infection.
- It is important that you tell your baby's doctor and other health care professionals at the clinic and well-baby clinic that you took Hyrimoz during your pregnancy before the baby receives any vaccine (for more information on vaccines see the 'Special warnings about using Hyrimoz' section).

Breastfeeding -
- Hyrimoz can be taken during breastfeeding.

Driving and using machines
Hyrimoz may have a minor influence on your ability to drive, cycle or use machines. Spinning sensation (vertigo) and vision disturbances may occur after taking Hyrimoz.

Important information about some of the ingredients in Hyrimoz
Hyrimoz contains less than 1 mmol of sodium (23 mg) per syringe, that is to say essentially 'sodium-free'.

3. How to use Hyrimoz?

Hyrimoz is administered by injection under the skin (by subcutaneous injection). Do not swallow 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.

How to use this medicine:
For detailed instructions on how to prepare and inject Hyrimoz see the section **'Instructions for use'.**

If you accidentally inject Hyrimoz more frequently than your doctor or pharmacist instructed you, contact your doctor or pharmacist immediately and tell them about it. Always take the outer carton of medicine with you, even if it is empty. If a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to give yourself a Hyrimoz injection at the scheduled time, inject a dose as soon as you remember. Then take your next dose according to your original schedule had you not forgotten a dose.

Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor.

If you stop using Hyrimoz your symptoms may return. The decision to stop treatment should be discussed with your doctor or pharmacist.

Do not take medicines in the dark! Check the label and the dose every time you take 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 Hyrimoz may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of 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 Hyrimoz injection.

Seek medical attention urgently, if you notice any of the following signs of allergic reaction or heart failure:
- severe rash, hives, or other signs of allergic reaction;
- swelling of the face, hands, feet;
- trouble breathing, trouble swallowing;
- shortness of breath with exertion or upon lying down, or swelling of the feet.

Tell your doctor as soon as possible, if you notice any of the following:
- signs and symptoms of infection such as fever, nausea, 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 bruise or an open sore that don't heal;
- signs and symptoms suggestive of blood disorders such as persistent fever, bruising, bleeding, paleness.

The following side effects have been observed with adalimumab:

Very common side effects (may affect more than 1 in 10 users):
- 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 side effects (may affect 1-10 in 100 users):
- serious infections (including blood poisoning and influenza);
- intestinal infections (including gastroenteritis);
- skin infections (including cellulitis and shingles);
- ear infections;
- infections in the mouth (including tooth infections and cold sores);
- reproductive tract infections;
- urinary tract infections;
- 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 tingling, prickling or numbness;
- migraine;
- nerve root compression (including low back pain and leg pain);
- vision disturbances;
- eye inflammation;
- inflammation of the eye lid and eye swelling;
- vertigo (sensation of spinning, dizziness);
- sensation of heart beating rapidly;
- high blood pressure;
- flushing;
- hematoma (collection 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;
- 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 cramps;
- blood in urine;
- kidney problems;
- chest pain;
- edema (a build-up of fluid in the body which causes the affected tissue to swell);
- fever;
- reduction in blood platelets which increases risk of bleeding or bruising;
- impaired healing.

Uncommon side effects (may affect 1-10 in 1,000 users):
- opportunistic infections (which include tuberculosis and other infections that occur when resistance to diseases is lowered);
- infections of the nervous system (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);
- inflammation of blood vessels (vasculitis);
- tremor;
- peripheral nerve disease (neuropathy);
- stroke;
- double vision;
- hearing loss, hearing a buzz;
- 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 space surrounding the lungs);
- inflammation of the pancreas which causes severe pain in the abdomen and back;
- difficulty in swallowing;
- facial edema (swelling of the face);
- gallbladder inflammation, gallbladder stones;
- fatty liver (build-up of fat in liver cells);
- night sweats;
- scarring;
- muscle breakdown;
- systemic lupus erythematosus (an autoimmune disorder including inflammation of skin, heart, lung, joints and other organs);
- sleep interruptions;
- impotence;
- inflammations.

Rare side effects (may affect 1-10 in 10,000 users):
- leukemia (cancer affecting the blood and bone marrow);
- severe allergic reaction with shock;
- multiple sclerosis;
- nerve disorders (such as inflammation of the eye nerve, and Guillain-Barré syndrome, a condition that may cause muscle weakness, abnormal sensations, tingling in the arms and upper body);
- heart stops pumping;
- scarring of the lung (pulmonary fibrosis);
- intestinal perforation (hole in the wall of the gut);
- liver inflammation (hepatitis);
- reactivation of viral hepatitis B infection;
- autoimmune hepatitis (inflammation of the liver caused by the body's own immune system);
- inflammation of blood vessels in the skin (cutaneous vasculitis);
- Stevens-Johnson syndrome (life-threatening reaction with flu-like symptoms and blistering rash);
- facial edema (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).

Side effects of unknown frequency (the frequency of these effects has not been established yet):
- 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 (in most patients, the weight gain was small).

Some side effects observed with adalimumab do not have symptoms and can only be discovered through blood tests. These include:
Very common side effects (may affect more than 1 in 10 users):
- low blood measurements for white blood cells;
- low blood measurements for red blood cells;
- increased lipids in the blood;
- raised liver enzymes.

Common side effects (may affect 1-10 in 100 users):
- 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 the enzyme lactate dehydrogenase;
- autoantibodies present in the blood;
- low blood measurements for potassium.

Uncommon side effects (may affect 1-10 in 1,000 users):
- high measurement for bilirubin (blood test for liver function).

Rare side effects (may affect 1-10 in 10,000 users):
- low blood measurements for white blood cells, red blood cells, and platelets.

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

Reporting side effects
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

5. How to store Hyrimoz?

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 a doctor.

Do not use Hyrimoz after the expiry date (exp. date) which is stated on the carton and the syringe. The expiry date refers to the last day of that month.

Storage conditions:
Store in a refrigerator (2°C – 8°C). **Do not freeze**. Keep in the outer carton in order to protect from light.
When needed (for example when you are travelling), Hyrimoz may be stored outside the refrigerator at a temperature of up to 25°C for a maximum period of 21 days (no later than the expiry date). Protect the syringe from light. Once removed from the refrigerator for room temperature storage **your syringe must be used within 21 days or discarded**, even if it is later returned to the refrigerator. You should record the date when your syringe is first removed from the 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. Additional information

What does Hyrimoz contain?
The active substance is adalimumab in prefilled syringe that is available in two volumes:
A pre-filled syringe that contains 40 mg of adalimumab in 0.8 ml of solution.
A pre-filled syringe that contains 20 mg of adalimumab in 0.4 ml of solution.
In addition to the active substance, this medicine also contains:
mannitol, sodium chloride, adipic acid, polysorbate 80, citric acid monohydrate, sodium hydroxide, hydrochloric acid, water for injection.

What Hyrimoz looks like and contents of the pack
Each pre-filled syringe contains 0.8 ml (40 mg) or 0.4 ml (20 mg) of clear to slightly opalescent, colorless to slightly yellowish solution.
Hyrimoz is supplied in a single-use pre-filled glass syringe with a stainless steel needle, a needle guard, finger flange, a rubber needle cap, and a plastic plunger rod.
Cartons contain one or two syringes in a blister. Multipack cartons contain 6 syringes (3 packs of 2 syringes each).

Not all pack sizes may be marketed.

License Holder and Importer's name and address:
Sandoz Pharmaceuticals Israel Ltd., P.O.Box 9015, Tel Aviv, Israel.

Revised in May 2023.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 164-72-36144-00

Instructions for using the Hyrimoz pre-filled syringe:

To help avoid possible infections and to ensure that you use the medicine correctly, it is important that you follow these instructions.
Be sure that you read, understand, and follow these Instructions for use before injecting Hyrimoz. Your doctor or nurse will show you how to prepare and inject Hyrimoz properly using the pre-filled syringe before you use it for the first time. Talk to your doctor or nurse if you have any questions.

Hyrimoz pre-filled syringe with needle guard and finger flange

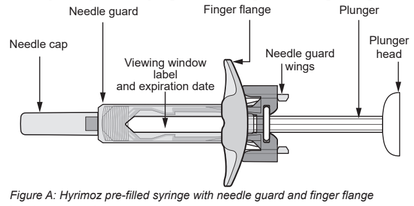


Figure A: Hyrimoz pre-filled syringe with needle guard and finger flange

It is important that you:
- **Do not open** the outer carton until you are ready to use the syringe.
- **Do not use** the syringe if the seal of the blister is broken as the medicine may not be safe for you to use.
- **Never leave** the syringe unattended where others might tamper with it.
- If you drop your syringe, **do not use it** if it looks damaged, or if you dropped it with the needle cap removed.
- **Do not remove** the needle cap until just before you give the injection
- **Do not touch** the needle guard wings before use. Touching them may cause the needle guard to be activated too early. **Do not remove** the finger flange before the injection.
- Inject Hyrimoz 15–30 minutes after taking it out of the refrigerator for a more comfortable injection.
- Throw away the used syringe right away after use. **Do not re-use a syringe**. See **4. 'Instructions for disposing of the used syringe'** at the end of these Instructions for Use.

How should you store Hyrimoz?
- Store your syringe inside its outer carton in a refrigerator (2°C to 8°C).
- When needed (for example when you are travelling), Hyrimoz may be stored outside the refrigerator at a temperature of up to 25°C for a maximum period of 21 days. Protect the syringe from light. Once removed from the refrigerator for room temperature storage, **your syringe must be used within 21 days or discarded**, even if it is later returned to the refrigerator. You should record the date when your syringe is first removed from the refrigerator, and the date after which it should be discarded.
- To protect from light, keep your syringes in the original carton until you are ready to use the medicine.
- Do not store your syringes in extreme heat or cold.
- Do not freeze your syringes.

Keep Hyrimoz and all medicines out of the reach of children.

What do you need for your injection?
Place the following items on a clean, flat surface.
Included in your carton is:
- Hyrimoz pre-filled syringe (see Figure A). Each syringe contains 20 mg in 0.4 ml of adalimumab or 40 mg in 0.8 ml of adalimumab.

Not included in your carton are (see Figure B):
- alcohol wipe
- cotton ball or gauze
- sharps disposal container

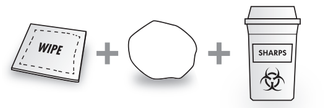


Figure B: Items not included in the carton

See **4. 'Instructions for disposing of the used syringe'** at the end of these Instructions for Use.

Before your injection

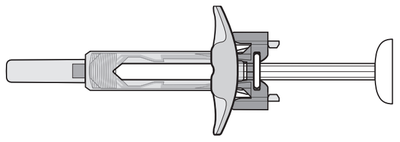


Figure C: In this position the needle guard is not activated – the syringe is ready for use

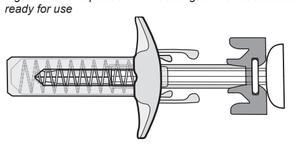


Figure D: In this position the needle guard is activated – do not use the syringe

Preparing the syringe
- For a more comfortable injection, take the blister containing the syringe out of the refrigerator and leave it unopened on your work surface for 15 to 30 minutes before injecting the medicine to allow it to reach room temperature.
- Take the syringe out of the blister.
- Look through the viewing window. The solution should be colorless to slightly yellowish as well as clear to slightly opalescent. Do not use if you see any particulates and/or discolorations. If you are concerned with the appearance of the solution, contact your pharmacist for assistance.
- Do not use the syringe if it is broken or the needle guard is activated. Return the syringe and the package it came in to the pharmacy
- Look at the expiration date (EXP) on your syringe. Do not use your syringe if the expiration date has passed.

Contact your pharmacist if the syringe fails any of the above mentioned checks.

1. Choosing your injection site:

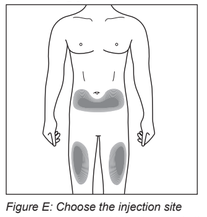


Figure E: Choose the injection site
- The recommended injection site is the front of your thighs. You may also use the lower abdomen, but not the area 5 cm around your navel (belly button) (see Figure E).
- Choose a different site each time you give yourself an injection.
- Do not inject into areas where the skin is tender, bruised, red, scaly, or hard. Avoid areas with scars or stretch marks.
  If you have psoriasis, you should NOT inject directly into areas with psoriasis plaques.

2. Cleaning your injection site:

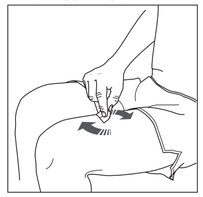


Figure F: Cleaning your injection site
- Wash your hands well with soap and water.
- Using a circular motion, clean the injection site with an alcohol wipe. Leave it to dry before injecting (see Figure F).
- Do not touch the cleaned area before injecting.

3. Giving your injection:

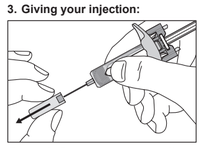


Figure G: Pull the needle cap off
- Carefully pull the needle cap off the syringe (see Figure G).
- Discard the needle cap.
- You may see a few drops of liquid at the end of the needle. This is normal.

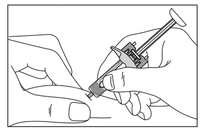


Figure H: Insert the needle
- Gently pinch the skin at the injection site (see Figure H).
- Insert the needle into your skin as shown in the figure.
- Push the needle all the way in to ensure that the medication can be fully administered.

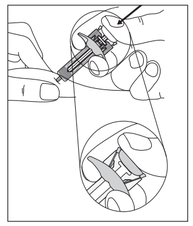


Figure I: Hold the syringe
- Hold the finger flange (see Figure I).
- Slowly press down on the plunger as far as it will go, so that the plunger head is completely between the needle guard wings.
- Keep the plunger pressed fully down while you hold the syringe in place for about 5 seconds.

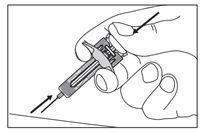


Figure J: Lift the needle straight out
- **Keep the plunger fully pressed down** while you carefully lift the needle straight out from the injection site and let go of your skin (see Figure J).

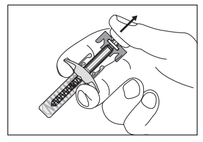
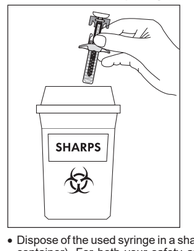


Figure K: Slowly release the plunger
- Slowly release the plunger and allow the needle safety guard to automatically cover the exposed needle (see Figure K).
- There may be a small amount of blood at the injection site. You can press a cotton ball or gauze onto the injection site and hold it for 10 seconds. Do not rub the injection site. You may cover the injection site with a small adhesive bandage, if needed.

4. Instructions for disposing of the used syringe:



- Dispose of the used syringe in a sharps container (closable, puncture-resistant container). For both your safety and health and that of others, never try to re-use needles and syringes.
- Do not throw away any medicines via wastewater or household waste. Ask your doctor or pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

If you have any questions, please talk to a doctor, pharmacist or nurse who is familiar with Hyrimoz.