

Package leaflet: Information for the patient

Hyrimoz 20 mg solution for injection in pre-filled syringe

adalimumab
20 mg/ 0.4 ml

Read all of this leaflet carefully before your child starts using this medicine because it contains important information.

- Keep this leaflet. You may need to read it again.
- If you have any questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child.
- If your child gets 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 Hyrimoz is and what it is used for
2. What you need to know before your child uses Hyrimoz
3. How to use Hyrimoz
4. Possible side effects
5. How to store Hyrimoz
6. Contents of the pack and other information
7. Instructions for use

1. What Hyrimoz is and what it is used for

Hyrimoz contains the active substance adalimumab.

Hyrimoz is intended for the treatment of the inflammatory diseases described below:

- Polyarticular juvenile idiopathic arthritis,
- Enthesitis-related arthritis
- Paediatric plaque psoriasis
- Paediatric Crohn's disease
- Paediatric uveitis.

The active ingredient in Hyrimoz, adalimumab, is a human monoclonal antibody. Monoclonal antibodies are proteins that attach to a specific target.

The target of adalimumab is a protein called tumour necrosis factor (TNF α), which is involved in the immune (defence) system and is present at increased levels in the inflammatory diseases listed above. By attaching to TNF α , Hyrimoz decreases the process of inflammation in these diseases.

Polyarticular juvenile idiopathic arthritis

Polyarticular juvenile idiopathic arthritis is an inflammatory disease of the joints that usually first appears in childhood.

Hyrimoz is used to treat polyarticular juvenile idiopathic arthritis in patients from 2 years of age. Your child may first be given other disease-modifying medicines, such as methotrexate. If these medicines do not work well enough, your child will be given Hyrimoz to treat his/her polyarticular juvenile idiopathic arthritis.

Your doctor will decide if Hyrimoz 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.

Hyrimoz is used to treat enthesitis-related arthritis in patients from 6 years of age. Your child may first be given other disease-modifying medicines, such as methotrexate. If these medicines do not work well enough, your child will be given Hyrimoz to treat his/her enthesitis-related arthritis.

Paediatric plaque psoriasis

Plaque psoriasis is a skin condition that causes red, flaky, crusty patches of skin covered with silvery scales. Plaque psoriasis can also affect the nails, causing them to crumble, become thickened and lift away from the nail bed which can be painful. Psoriasis is believed to be caused by a problem with the body's immune system that leads to an increased production of skin cells.

Hyrimoz is used to treat 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.

Paediatric Crohn's disease

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

Hyrimoz is used to treat moderate to severe Crohn's disease in children and adolescents aged 6 to 17 years.

Your child may first be given other medicines. If these medicines do not work well enough, your child will be given Hyrimoz to reduce the signs and symptoms of his/her disease.

Paediatric uveitis

Non-infectious uveitis is an inflammatory disease affecting certain parts of the eye.

Hyrimoz is used to treat children with chronic non-infectious uveitis from 2 years of age with inflammation affecting the front of the eye.

This inflammation may lead to a decrease of vision and/or the presence of floaters in the eye (black dots or wispy lines that move across the field of vision). Hyrimoz works by reducing this inflammation.

Your child may first be given other medicines. If these medicines do not work well enough, your child will be given Hyrimoz to reduce the signs and symptoms of his/her disease.

Paediatric ulcerative colitis

Ulcerative colitis is an inflammatory disease of the large intestine.

Hyrimoz is used to treat moderate to severe ulcerative colitis in children and adolescents aged 5 to 17 years.

Your child may first be given other medicines. If these medicines do not work well enough, your child will be given Hyrimoz to reduce the signs and symptoms of his/her disease.

2. What you need to know before your child uses Hyrimoz

Do not use Hyrimoz

- If your child is allergic to adalimumab or any of the other ingredients of this medicine (listed in section 6).
- If your child has active tuberculosis or other severe infections (see “Warnings and precautions”). It is important that you tell your doctor if your child has symptoms of infections, for example, fever, wounds, feeling tired, dental problems.
- If your child has moderate or severe heart failure. It is important to tell your doctor if your child has had or has a serious heart condition (see “Warnings and precautions”).

Warnings and precautions

Talk to your doctor or pharmacist before using Hyrimoz.

Allergic reactions

- If your child gets allergic reactions with symptoms such as chest tightness, wheezing, dizziness, swelling or rash do not inject more Hyrimoz and contact your doctor immediately since, in rare cases, these reactions can be life threatening.

Infections

- If your child has an infection, including long-term infection or an infection in one part of the body (for example, leg ulcer) consult your doctor before starting Hyrimoz. If you are unsure, contact your doctor.
- Your child might get infections more easily while he/she is receiving Hyrimoz treatment. This risk may increase if your child has problems with his/her lungs. These infections may be serious and include:
 - tuberculosis
 - infections caused by viruses, fungi, parasites or bacteria
 - severe infection in the blood (sepsis)

In rare cases, these infections can be life-threatening. It is important to tell your doctor if your child gets symptoms such as fever, wounds, feeling tired or dental problems. Your doctor may tell you to stop using Hyrimoz for some time.

- Tell your doctor if your child lives or travels in regions where fungal infections (for example, histoplasmosis, coccidioidomycosis or blastomycosis) are very common.
- Tell your doctor if your child has had infections which keep coming back or other conditions that increase the risk of infections.
- Your child and his/her doctor should pay special attention to signs of infection while your child is being treated with Hyrimoz. It is important to tell your doctor if your child gets symptoms of infections, such as fever, wounds, feeling tired or dental problems.

Tuberculosis

- As cases of tuberculosis have been reported in patients treated with Hyrimoz, your doctor will check your child for signs and symptoms of tuberculosis before starting Hyrimoz. This will include a thorough medical evaluation including your child's medical history and appropriate screening tests (for example, chest X-ray and a tuberculin test).
- It is very important that you tell your doctor if your child has ever had tuberculosis, or if your child has been in close contact with someone who has had tuberculosis. If your child has active tuberculosis, do not use Hyrimoz.
- Tuberculosis can develop during therapy even if your child has received treatment for the prevention of 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

- Tell your doctor if your child is a carrier of the hepatitis B virus (HBV), if he/she has active HBV or if you think he/she might be at risk of getting HBV.
 - Your doctor should test your child for HBV. In people who carry HBV, Hyrimoz can cause the virus to become active again.
 - In some rare cases, especially if your child is taking other medicines that suppress the immune system, reactivation of HBV can be life-threatening.

Surgery or dental procedure

- If your child is about to have surgery or dental procedures please inform your doctor that your child is taking Hyrimoz. Your doctor may recommend temporary discontinuation of Hyrimoz.

Demyelinating disease

- If your child has or develops a demyelinating disease (a disease that affects the insulating layer around the nerves, such as multiple sclerosis), your doctor will decide if he/she should receive or continue to receive Hyrimoz. Tell your doctor immediately if your child experiences symptoms like changes in vision, weakness in arms or legs or numbness or tingling in any part of the body.

Vaccinations

- Certain vaccines may cause infections and should not be given while receiving Hyrimoz.
 - Check with your doctor before your child receives any vaccines.
 - It is recommended that children, if possible, be given all the scheduled vaccinations for their age before they start treatment with Hyrimoz.
 - If your child received Hyrimoz while she was pregnant, her baby may be at higher risk for getting such an infection for up to approximately five months after the last Hyrimoz dose she received during pregnancy. It is important that you tell her baby's doctors and other health care professionals about your child's Hyrimoz use during her pregnancy so they can decide when her baby should receive any vaccine.

Heart failure

- If your child has mild heart failure and is being treated with Hyrimoz, his/her heart failure status must be closely monitored by your doctor. It is important to tell your doctor if your child has had or has a serious heart condition. If he/she develops 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 your child should receive Hyrimoz.

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 your child to stop bleeding. Your doctor may decide to stop treatment. If your child develops a fever that does not go away, develops light bruises or bleeds very easily or looks very pale, call your doctor right away.

Cancer

- There have been very rare cases of certain kinds of cancer in children and adult patients taking Hyrimoz or other TNF blockers.
 - People with more serious rheumatoid arthritis that have had the disease for a long time may have a higher than average risk of getting lymphoma (a cancer that affects the lymph system) and leukaemia (a cancer that affects the blood and bone marrow).
 - If your child takes Hyrimoz the risk of getting lymphoma, leukaemia, or other cancers may increase. On rare occasions, an uncommon and severe type of lymphoma, has been seen in patients taking Hyrimoz. Some of those patients were also treated with azathioprine or 6-mercaptopurine.
 - Tell your doctor if your child is taking azathioprine or 6-mercaptopurine with Hyrimoz.
 - Cases of non-melanoma skin cancer have been observed in patients taking Hyrimoz.
 - If new skin lesions appear during or after therapy or if existing lesions change appearance, tell your doctor.
- There have been cases of cancers, other than lymphoma in patients with a specific type of lung disease called Chronic Obstructive Pulmonary Disease (COPD) treated with another TNF blocker. If your child has COPD, or is a heavy smoker, you should discuss with your doctor whether treatment with a TNF blocker is appropriate for your child.

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.

Other medicines and Hyrimoz

Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines.

Your child should not take Hyrimoz with medicines containing the following active substances due to increased risk of serious infection:

- Anakinra
- Abatacept

Hyrimoz can be taken together with:

- Methotrexate

- Certain disease-modifying anti-rheumatic agents (for example, sulfasalazine, hydroxychloroquine, leflunomide and injectable gold preparations)
- Steroids or pain medications including non-steroidal anti-inflammatory drugs (NSAIDs).

If you have questions, please ask your doctor.

Pregnancy and breast-feeding

Hyrimoz should only be used during a pregnancy if needed. You or your child should consider the use of adequate contraception to prevent pregnancy and continue its use for at least 5 months after the last Hyrimoz treatment.

- You should talk to your doctor if you become pregnant or are planning to have a baby.
- You should talk to your doctor if you are breastfeeding or plan to breastfeed.
- If you received Hyrimoz during pregnancy, your baby may have a higher risk of getting an infection.
- It is important that you tell your baby's doctors and other health care professionals about your Hyrimoz use during your pregnancy before the baby receives any vaccine.

Driving and using machines

Hyrimoz may have a small effect on your child's ability to drive, cycle or use machines. Room spinning sensation and vision disturbances may occur after taking Hyrimoz.

3. How to use Hyrimoz

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended doses for Hyrimoz in each of the approved uses are shown in the following table. Your doctor may prescribe another strength of Hyrimoz if your child needs a different dose.

Polyarticular juvenile idiopathic arthritis		
Age or body weight	How much and how often to take?	Notes
Children, adolescents and adults from 2 years of age weighing 30 kg or more	40 mg every other week	Not applicable
Children and adolescents from 2 years of age weighing 10 kg to less than 30 kg	20 mg every other week	Not applicable

Enthesitis-related arthritis		
Age or body weight	How much and how often to take?	Notes
Children, adolescents and adults from 6 years of age weighing 30 kg or more	40 mg every other week	Not applicable
Children and adolescents from 6 years of age weighing 15 kg to less than 30 kg	20 mg every other week	Not applicable

Paediatric plaque psoriasis		
Age or body weight	How much and how often to take?	Notes
Children and adolescents from 4 to 17 years of age weighing 30 kg or more	First 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	First dose of 20 mg, followed by 20 mg one week later. Thereafter, the usual dose is 20 mg every other week.	Not applicable

Paediatric Crohn's disease		
Age or body weight	How much and how often to take?	Notes
Children and adolescents from 6 to 17 years of age weighing 40 kg or more	First dose of 80 mg, followed by 40 mg two weeks later. If a faster response is required, your child's doctor may prescribe a first dose of 160 mg, followed by 80 mg two weeks later. Thereafter, the usual dose is 40 mg every other week.	Your child's doctor may increase the dose frequency to 40 mg every week or 80 mg every other week.
Children and adolescents from 6 to 17 years of age weighing less than 40 kg	First dose of 40 mg, followed by 20 mg two weeks later. If a faster response is required, the doctor may prescribe a first dose of 80 mg, followed by 40 mg two weeks later. Thereafter, the usual dose is 20 mg every other week.	Your child's doctor may increase the dose frequency to 20 mg every week.

Paediatric uveitis		
Age or body weight	How much and how often to take?	Notes
Children and adolescents from 2 years of age weighing less than 30 kg	20 mg every other week	Your doctor may prescribe an initial dose of 40 mg to be administered one week prior to the start of the usual dose of 20 mg every other week. Hyrimoz is recommended for use in combination with methotrexate.

Children and adolescents from 2 years of age weighing 30 kg or more	40 mg every other week	Your doctor may prescribe an initial dose of 80 mg to be administered one week prior to the start of the usual dose of 40 mg every other week. Hyrimoz is recommended for use in combination with methotrexate.
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Paediatric ulcerative colitis		
Age or body weight	How much and how often to take?	Notes
Children and adolescents from 5 years of age weighing less than 40 kg	First dose of 80 mg, followed by 40 mg two weeks later. Thereafter, the usual dose is 40 mg every other week or 20 mg every week.	You should continue taking Hyrimoz at your usual dose, even after turning 18 years of age.
Children and adolescents from 5 years of age weighing 40 kg or more	First dose of 160 mg, followed by 80 mg two weeks later. Thereafter, the usual dose is 80 mg every other week or 40 mg every week.	You should continue taking Hyrimoz at your usual dose, even after turning 18 years of age.

Method and route of administration

Hyrimoz is administered by injection under the skin (by subcutaneous injection).

Detailed instructions on how to inject Hyrimoz are provided in section 7, “**Instructions for use**”.

If you use more Hyrimoz than you should

If you accidentally inject Hyrimoz more frequently than told to by your doctor or pharmacist, call your doctor or pharmacist and tell them that your child has taken more. Always take the outer carton of the medicine with you, even if it is empty.

If you forget to use Hyrimoz

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

If you stop using Hyrimoz

The decision to stop using Hyrimoz should be discussed with your doctor. Your child’s symptoms may return upon stopping treatment.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Most side effects are mild to moderate. However, some may be serious and require treatment. Side effects may occur at least up to 4 months after the last Hyrimoz injection.

Tell your doctor immediately if you notice any of the following

- severe rash, hives or other signs of allergic reaction
- 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 of infection such as fever, feeling sick, wounds, dental problems, burning on urination
- feeling weak or tired
- coughing
- tingling
- numbness
- double vision
- arm or leg weakness
- 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 Hyrimoz.

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 pain
- nausea and vomiting
- rash
- musculoskeletal pain

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
- oral 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
- 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 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
- cancer that affects the lymph system
- melanoma
- immune disorders that could affect the lungs, skin and lymph nodes (most commonly presenting as sarcoidosis)
- 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
- night sweats
- scar
- abnormal muscle breakdown
- systemic lupus erythematosus (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 eye nerve inflammation and Guillain-Barré syndrome 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 intestine)
- hepatitis

- reactivation of hepatitis B
- 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 of the face) 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 the available data)

- hepatosplenic T-cell lymphoma (a rare blood cancer that is often fatal)
- Merkel cell carcinoma (a type of skin cancer)
- liver failure
- worsening of a condition called dermatomyositis (seen as a skin rash accompanying muscle weakness)

Some side effects observed with Hyrimoz 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
- elevated 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)

- elevated bilirubin measurement (liver blood test)

Rare (may affect up to 1 in 1,000 people)

- low blood measurements for white blood cells, red blood cells and platelet count

Reporting of side effects

If your child gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store Hyrimoz

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/blister/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), Hyrimoz may be stored at room temperature (up to 25°C) for a maximum period of 21 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 21 days or discarded**, even if it is later returned to the refrigerator. You should record the date when your pre-filled syringe is first removed from the refrigerator, and the date after which it should be discarded.

When needed (for example when you are travelling), Hyrimoz 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 your pre-filled 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. Contents of the pack and other information

What Hyrimoz contains

- The active substance is adalimumab. Each pre-filled syringe contains 20 mg of adalimumab in 0.4 ml of solution.
- The other ingredients are adipic acid, citric acid monohydrate, sodium chloride, mannitol, polysorbate 80, hydrochloric acid, sodium hydroxide and water for injections (see section 2 “Hyrimoz contains sodium”).

What Hyrimoz looks like and contents of the pack

Hyrimoz 20 mg solution for injection (injection) in pre-filled syringe for paediatric use is supplied as a 0.4 ml clear to slightly opalescent, colourless or slightly yellowish solution.

Hyrimoz is supplied in a single-use clear type I glass syringe with a stainless steel 29 gauge needle with a needle guard with finger flange, rubber needle cap (thermoplastic elastomer) and plastic plunger rod, containing 0.4 ml of solution.

Carton contains 2 pre-filled syringes of Hyrimoz.

Not all pack sizes may be marketed.

Hyrimoz is available as a pre-filled syringe and a pre-filled pen.

Product Registrant

Sandoz Singapore Pte. Ltd.
10 Collyer Quay #10-01
Ocean Financial Centre
Singapore 049315

This leaflet was last revised in Mar 2024.

7. Instructions for use

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 healthcare provider should 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 healthcare provider if you have any questions.

Your Hyrimoz single-use pre-filled syringe with needle guard and add-on finger flange

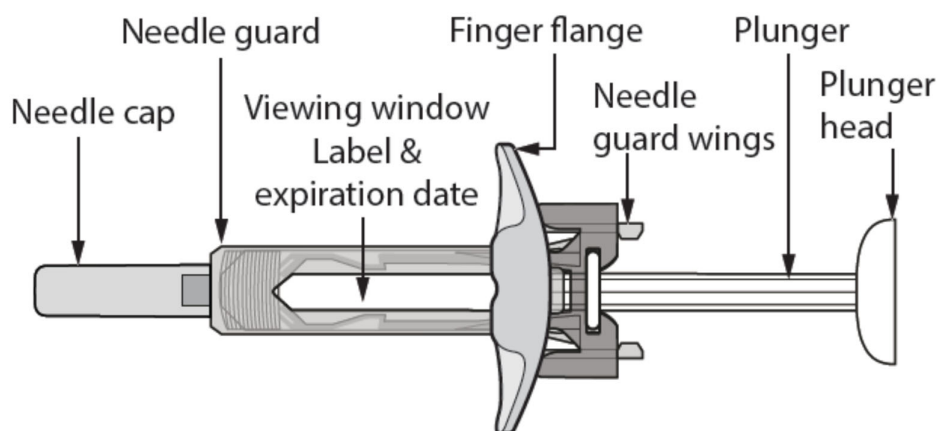


Figure A: Hyrimoz pre-filled syringe with needle guard and add-on finger flange

It is important that you:

- **do not open** the outer box until you are ready to use the syringe.
- **do not use** the syringe if the seals of the blister are broken, as it 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.
- be careful **not to 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. Disposing of used syringes” at the end of these Instructions for Use.

How should you store Hyrimoz?

- Store your outer carton of syringes in a refrigerator, between 2°C to 8°C.
- When needed (for example when you are travelling), Hyrimoz 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 your pre-filled syringe is first removed from the refrigerator, and the date after which it should be discarded.
- Keep the syringes in the original carton until ready to use to protect from light.
- Do not store the syringes in extreme heat or cold.

- Do not freeze the 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/s (see *Figure A*). Each syringe contains 20 mg/0.4 ml of Hyrimoz.

Not included in your carton are (see *Figure B*):

- Alcohol wipe
- Cotton ball or gauze
- Sharps disposal container

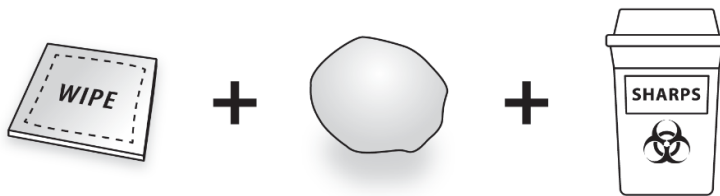


Figure B: items not included in the carton

See “4. **Disposing of used syringes**” at the end of these Instructions for Use.

Before your injection

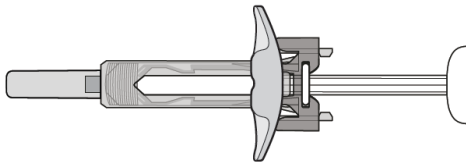


Figure C: needle guard is not activated – the syringe is ready for use

- In this configuration the needle guard is **NOT ACTIVATED**.
- The syringe is ready for use (see *Figure C*).

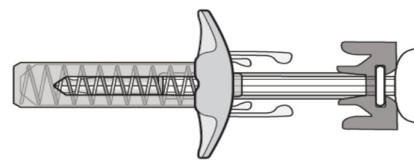


Figure D: needle guard is activated – do not use

- In this configuration the needle guard is **ACTIVATED**.
- **DO NOT USE** the syringe (see *Figure D*).

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 about 15 to 30 minutes so that it reaches room temperature.
- Take the syringe out of the blister.
- Look through the viewing window. The solution should be colourless or slightly yellowish as well as clear to slightly opalescent. Do not use if any particulates and/or discolorations are observed. If you are concerned with the appearance of the solution, then 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 expiry date (EXP) on your syringe. Do not use the syringe if the expiry date has passed.

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

1. Choosing your 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.

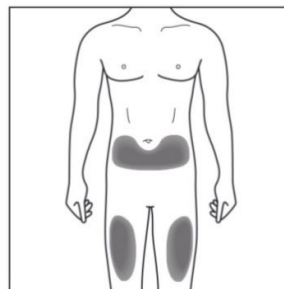


Figure E: choose your injection site

2. 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.

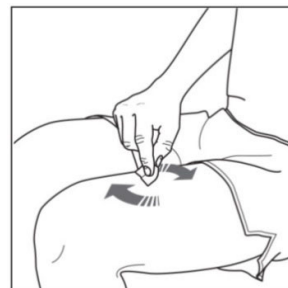


Figure F: clean your injection site

3. Giving your injection:

- Carefully pull the needle cap straight off to remove it from the syringe (see *Figure G*).
- Discard the needle cap.
- You may see a drop of liquid at the end of the needle. This is normal.

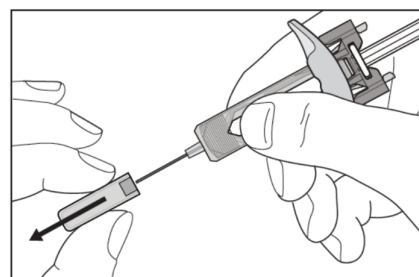


Figure G: pull the needle cap off

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

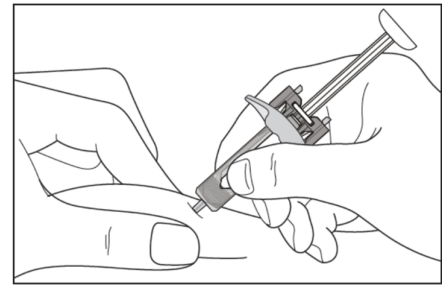


Figure H: insert the needle

- Hold the syringe as shown (*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 5 seconds.

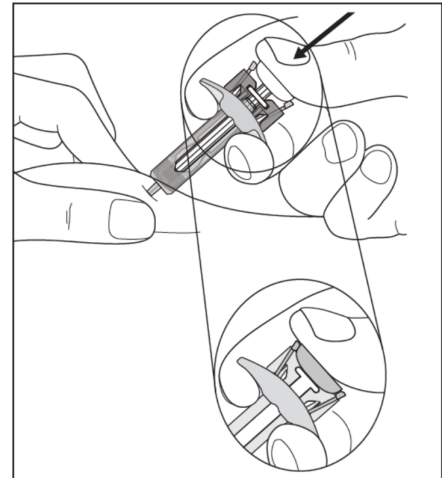


Figure I: hold the syringe

- **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*).

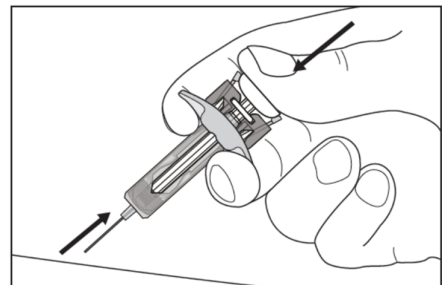


Figure J: lift the needle straight out

- 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.

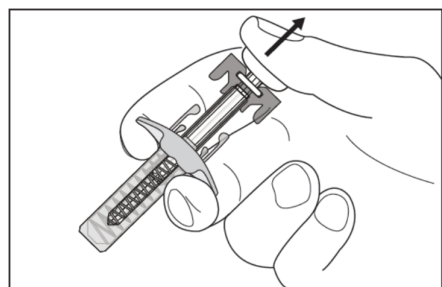
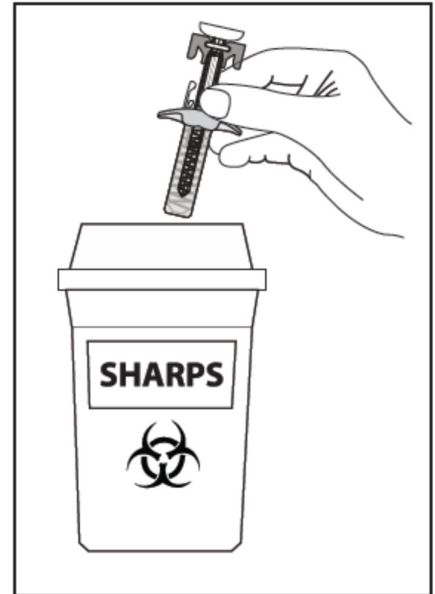


Figure K: slowly release the plunger

4. Disposing of used syringes:

- Dispose of the used syringe in a sharps container (closable, puncture-resistant container). For the safety and health of you and others, needles and used syringes must never be re-used.
- 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. Any unused product or waste material should be disposed of in accordance with local requirements.



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