

HYRIMOZ SOLUTION FOR INJECTION IN PRE-FILLED PEN

Adalimumab (40mg/0.8ml)

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What Hyrimoz is used for

Hyrimoz is intended for treatment of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis aged above 2 years old, axial spondyloarthritis (ankylosing spondylitis and Non-radiographic axial spondyloarthritis), psoriatic arthritis, enthesitis-related arthritis in children aged 6 years and above, psoriasis in adults and children aged 4 years and above, Crohn's disease in adults and children aged 6 years and above, ulcerative colitis in adults and children aged 6 years and above, hidradenitis suppurativa in adults and adolescents, and uveitis in adults and children aged 2 years and above.

How Hyrimoz works

It is a medicine that decreases the inflammation process of these diseases. The active ingredient, adalimumab, is a human monoclonal antibody produced by cultured cells. Monoclonal antibodies are proteins that recognise and bind to other unique proteins. Adalimumab binds to a specific protein (tumour necrosis factor or TNF α), which is present at increased levels in inflammatory diseases such as rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, axial spondyloarthritis (ankylosing spondylitis and Non-radiographic axial spondyloarthritis), psoriatic arthritis, psoriasis, ulcerative colitis, hidradenitis suppurativa, Crohn's disease, Uveitis and Enthesitis-Related Arthritis.

Before you use Hyrimoz

- When you must not use it

- If you are allergic (hypersensitive) to adalimumab or any of the other ingredients of Hyrimoz.
- If you have a severe infection, including active tuberculosis. It is important that you tell your doctor if you have symptoms of infections, e.g. fever, wounds, feeling tired, dental problems.
- If you have moderate or severe heart failure. It is important to tell your doctor if you have had or have a serious heart condition.

Pregnancy and lactation

You should talk to your doctor if you become pregnant or are planning to have a baby.

According to a pregnancy study, there was no higher risk of birth defects when the mother had received Hyrimoz during pregnancy compared with mothers with the same disease who did not receive Hyrimoz.

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.

- Before you start use it

- If you have an infection, including long-term or localized infection (for example, leg ulcer) consult your doctor before starting Hyrimoz.
- As cases of tuberculosis have been reported in patients treated with Hyrimoz, your doctors will check you for sign and symptoms of tuberculosis before starting Hyrimoz.
- Advise your doctor if you reside or travel in regions where fungal infections such as histoplasmosis

coccidioidomycosis or blastomycosis are epidemic.

- Advise your doctor if you are a carrier of the hepatitis B virus (HBV), if you have active HBV or if you think you might be at risk of contracting HBV. Your doctor should test you for HBV. Hyrimoz can cause reactivation of HBV in people who carry this virus. In some rare cases, especially if you are taking other medicines that suppress the immune system, reactivation of HBV can be life-threatening.
- Advise your doctor if you have a history of recurrent infections or other conditions that increase the risk of infections.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop. Live vaccines may cause infections and should not be given while receiving Hyrimoz.

You should not take Hyrimoz with medicines containing the active substance, anakinra or abatacept. If you have questions, please ask your doctor.

How to use Hyrimoz

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Hyrimoz for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

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Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

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

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Hyrimoz.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

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

- Things to be careful of

Driving and using machines

Hyrimoz may have a minor influence on your ability to drive and use machines. Room spinning sensation and vision disturbances may occur after taking Hyrimoz.

Side effects

Like all medicines, Hyrimoz can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine:

- Severe rash, hives or other signs of allergic reaction;
- Swollen face, hands, feet;
- Trouble breathing, swallowing;
- Shortness of breath with exertion or upon lying down or swelling of the feet;
- Signs and symptoms suggestive of blood disorders such as persistent fever, bruising, bleeding, paleness;

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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects of Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Hyrimoz

- Storage

Store in a refrigerator (2°C–8°C).

Do not freeze.

Keep the pre-filled pen in the outer carton in order to protect from light.

Do not use Hyrimoz pre-filled pen after the expiry date stated on the label/carton after EXP:. The expiry date refers to the last day of that month.

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 pen must be used within 21 days or discarded, even if it is later returned to the refrigerator.

OR

Hyrimoz may be stored at 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 pen 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 pen is first removed from the refrigerator, and the date after which it should be discarded.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Hyrimoz 40 mg solution for injection (injection) in pre-filled pen is supplied as a 0.8 ml clear to slightly opalescent, colourless or slightly yellowish solution.

Cartons contain 1 and 2 pre-filled pens of Hyrimoz.

- Ingredients

- **Active ingredient**
Adalimumab

- **Inactive ingredients**

Adipic acid
Citric acid monohydrate

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Sodium chloride
Mannitol
Polysorbate 80
Hydrochloric acid (for pH adjustment)
Sodium hydroxide (for pH adjustment)
Water for injections

- MAL number:
MAL22016007ACZ

Manufacturer and Batch Releaser

Novartis Pharmaceutical Manufacturing
GmbH
Biochemiestrasse 10
6336 Langkampfen
Austria

Product Registration Holder

Sandoz Products Malaysia Sdn. Bhd.
Unit 1202, Level 12, Uptown 1,
No. 1, Jalan SS 21/58, Damansara Uptown,
47400 Petaling Jaya, Selangor, Malaysia

Date of revision

05/08/2025

Serial number

NPRA (R3/1)21/11

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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 pen before you use it for the first time. Talk to your healthcare provider if you have any questions.

Your Hyrimoz single-use pre-filled SensoReady pen

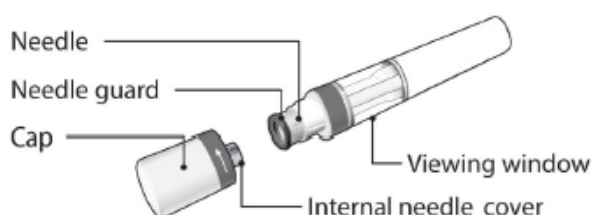


Figure A: Hyrimoz SensoReady pen parts

In Figure A, the pen is shown with the cap removed. **Do not** remove the cap until you are ready to inject.

It is important that you:

- **do not open** the outer box until you are ready to use the pen.
- **do not use** the pen if either the seal on the outer carton or the safety seal on the pen is broken.
- **never leave** the pen unattended where others might tamper with it.
- if you drop your pen, **do not use** it if it looks damaged, or if you dropped it with the cap removed.
- inject Hyrimoz 15–30 minutes after taking it out of the refrigerator for a more comfortable injection.
- throw away the used pen right away after use. **Do not re-use the pen.** See “8. Disposing of used pens” at the end of this Instructions for Use.

How should you store your pen?

- Store your pen within the carton 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 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 pen **must be used within 21 days or discarded**, even if it is later returned to the refrigerator.

OR

Hyrimoz may be stored at 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 pen **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 pen is first removed from the refrigerator, and the date after which it should be discarded.

- Keep your pen in the original carton until ready to use to protect from light.
- Do not store your pen in extreme heat or cold.
- Do not freeze your pen.

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:

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- Hyrimoz pre-filled SensoReady pen/s (see *Figure A*). Each pen contains 40 mg/0.8 ml of Hyrimoz.

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

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

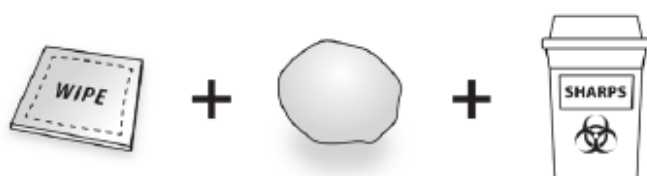


Figure B: items not included in the carton

See “8. Disposing of used pens” at the end of these Instructions for Use.

Before your injection

Preparing the pen

- For a more comfortable injection, take your pen out of the refrigerator 15 to 30 minutes before injecting Hyrimoz to allow it to reach room temperature.
- Look through the viewing window. The solution should be clear to slightly opalescent, colourless or slightly yellowish solution. **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.

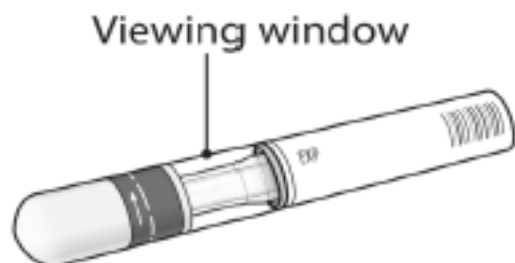


Figure C: Safety Checks before injection

- Look at the expiration date (EXP) on your pen. Do not use your pen if the expiration date has passed.
- Do not use if the safety seal has been broken

Contact your pharmacist if the pen 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 5cm around your navel (belly button) (see *Figure D*).
- 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.

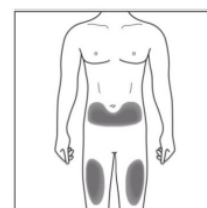


Figure D: choose your injection site

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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 E*).
- Do not touch the cleaned area again before injecting.



Figure E: clean your injection site

3. Removing the cap of the pen

- Only remove the cap when you are ready to use the pen.
- Twist off the cap in the direction of the arrows (*see Figure F*).
- Once removed, throw away the cap. **Do not try to re-attach the cap.**
- Use your pen within 5 minutes of removing the cap.
- You may see a few drops of liquid come out of the needle. This is normal.

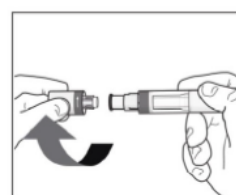


Figure F: remove the cap

4. Holding the pen

- Hold your pen at 90° to the cleaned injection site (*see Figure G*)

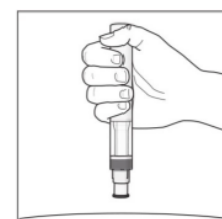
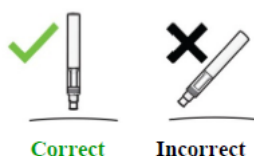


Figure G: hold your pen

Your injection

You must read this before injecting

During the injection you will hear **2 loud clicks**:

- The **1st click** indicates that the injection has **started**.
- Several seconds later a **2nd click** will indicate that the injection is **almost** finished.

You must keep holding your pen firmly against your skin until you see a **green indicator** fill the window and stop moving.

5. Starting your injection:

- Press your pen firmly against the skin to start the injection (*see Figure H*).
- The **1st click** indicates the injection has started.
- **Keep holding** your pen firmly against your skin.
- The **green indicator** shows the progress of the injection.

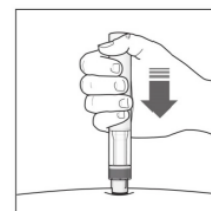


Figure H: start your injection

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6. Completing your injection:

- Listen for the **2nd click**. This indicates the injection is **almost complete**.
- Check the **green indicator** fills the window and has stopped moving (*see Figure I*).
- The pen can now be removed.

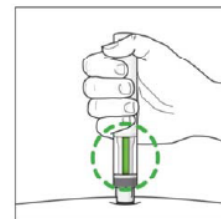


Figure I: complete your injection

After your injection

7. Check the green indicator fills the window (*see Figure J*):

- This means the medicine has been delivered. Contact your doctor if the green indicator is not visible.
- There may be a small amount of blood at the injection site. You can press a cotton ball or gauze over 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.

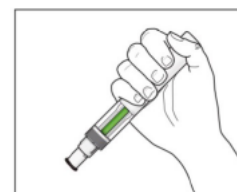
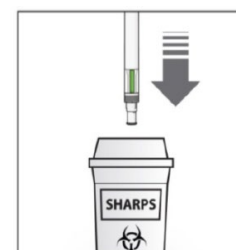


Figure J: check the green indicator

8. Disposing of used pens:

- Dispose of the used pens in a sharps container (closable, puncture resistant container). For the safety and health of you and others, the pens 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.