PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

HYRIMOZ® 40 mg / 0,8 mL (Solution for Injection)

Adalimumab

Sugar free

Read all of this leaflet carefully before you start using HYRIMOZ.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse, or other health care provider.
- HYRIMOZ has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What HYRIMOZ is and what it is used for
2. What you need to know before you use HYRIMOZ
3. How to use HYRIMOZ
4. Possible side effects
5. How to store HYRIMOZ
6. Contents of the pack and other information

1. What HYRIMOZ is and what it is used for

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 (TNFα), which is involved in the immune (defence) system and is present at increased levels in the inflammatory diseases listed below. By attaching to TNFα, HYRIMOZ decreases the process of inflammation in these diseases. HYRIMOZ is intended for the treatment of the inflammatory diseases below:

Adults:

Rheumatoid Arthritis is an inflammatory disease of the joints. HYRIMOZ is used to treat rheumatoid arthritis in adults.

Psoriatic Arthritis is an inflammation of the joints associated with psoriasis. HYRIMOZ is used to treat psoriatic arthritis in adults.

Plaque Psoriasis is a skin condition that causes red, flaky, crusty patches of skin covered with silvery scales. HYRIMOZ is used to treat plaque psoriasis in adults. HYRIMOZ is indicated for moderate to severe **nail psoriasis** in adult patients who are candidates for systemic therapy.

Axial Spondyloarthritis including ankylosing spondylitis is the inflammatory diseases of the spine. HYRIMOZ is used to treat axial spondyloarthritis in adults.

Ankylosing Spondylitis is the inflammatory diseases of the spine. HYRIMOZ is used to treat ankylosing spondylitis in adults.

Crohn's disease is an inflammatory disease of the digestive tract. HYRIMOZ is used to treat Crohn's disease in adults.

Ulcerative colitis is an inflammatory disease of the bowel. HYRIMOZ is used to treat ulcerative colitis in adults.

Hidradenitis Suppurativa (sometimes called acne inversa) is a chronic and often painful inflammatory skin disease. Symptoms may include tender nodules (lumps) and abscesses (boils) that may leak pus. It most commonly affects specific areas of the skin, such as under the breasts, the armpits, inner thighs, groin and buttocks. Scarring may also occur in affected areas. HYRIMOZ is used to treat hidradenitis suppurativa in adults.

Uveitis is an inflammatory disease affecting certain parts of the eye. HYRIMOZ is used to treat adults with non-infectious uveitis.

Paediatrics:

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.

Paediatric Crohn's Disease is an inflammatory disease of the digestive tract. HYRIMOZ is used to Crohn's disease in children and adolescents from 6 years of age and older.

Paediatric Plaque Psoriasis is a skin condition that causes red, flaky, crusty patches of skin covered with silvery scales. HYRIMOZ is used to treat plaque psoriasis in children and adolescents from 4 years of age.

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.

2. What you need to know before you use HYRIMOZ

Do not use HYRIMOZ:

- If you are allergic (hypersensitive) to adalimumab or any of the other ingredients of HYRIMOZ (listed in section 6).
- If you have a severe infection, including active tuberculosis, see "Take special care with HYRIMOZ". It is important that you tell your doctor if you have symptoms of infections, e.g., fever, wounds, feeling tired, dental problems.
- If you have moderate or severe heart failure. It is important to tell your doctor if you have had or have a serious heart condition, see "Take special care with HYRIMOZ".
- If you are to receive live vaccines, they should not be given while receiving HYRIMOZ. Please check with your doctor before you receive any vaccines.

Warnings and precautions:

Take special care with HYRIMOZ:

- If you experience allergic reactions such as chest tightness, wheezing, dizziness, difficulty to breath, swelling of the face, hands, feet, throat, or rash; do not inject more HYRIMOZ and contact your doctor immediately.
- The needle cover of the syringe contains natural rubber (latex). This may cause severe allergic reactions in patients sensitive to latex. Patients who have a known sensitivity to latex should be advised to avoid touching the inner shield.
- If you have an infection, including long-term or localised infection (for example, leg ulcer) consult your doctor before starting HYRIMOZ. If you are unsure, please contact your doctor.
- You might get infections more easily while you are receiving HYRIMOZ treatment including serious infections, tuberculosis, opportunistic infections and sepsis that may be life threatening. It is important to tell your doctor if you get symptoms such as fever, wounds, feeling tired or dental problems.
- As cases of tuberculosis have been reported in patients treated with HYRIMOZ, 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 appropriate screening tests – (for example a chest x-ray and a tuberculin test). The conduct and results of these tests should be recorded.

  It is very important that you tell your doctor if you have ever had tuberculosis. Tuberculosis can develop during therapy even if you have received preventative treatment for tuberculosis. If symptoms of tuberculosis (persistent cough, weight loss, listlessness, mild fever), or any other infections appear during or after therapy tell your doctor immediately.
- Advise your doctor if you have a history of recurrent infections or other conditions that increase the risk of infections.
- 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. HYRIMOZ can cause reactivation of HBV in people who carry this virus. In some cases, especially if you are taking other medicines that suppress the immune system, reactivation of HBV can be life threatening.
- If you are about to undergo surgery or dental procedures, please inform your doctor that you are using HYRIMOZ.
- 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.

- Some vaccines should not be given during treatment with HYRIMOZ. Please check with your doctor before you receive any vaccines.
- If you have mild heart failure and you are being treated with HYRIMOZ, your heart failure status must be closely monitored by your doctor. It is important to tell your doctor if you have had or have a serious heart condition. If you develop new or worsening symptoms of heart failure (e.g., shortness of breath, or swelling of your feet), you must contact your doctor immediately.
- In some patients, the body may fail to produce enough of the blood cells that help your body fight infections or help you to stop bleeding. If you develop a fever that does not go away, bruise or bleed very easily or look very pale, call your doctor right away. Your doctor may decide to stop treatment.
- There have been cases of certain kinds of cancer in 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 a kind of cancer that affects the lymph system (lymphoma) or the cancer of the white blood cells (leukaemia). If you take HYRIMOZ your risk may increase. In addition, cases of non-melanoma skin cancer have been observed in patients taking HYRIMOZ.
- Cancers, other than lymphoma, have been reported in patients with a specific type of lung disease called Chronic Obstructive Pulmonary Disease (COPD) treated with another TNF blocker. If you have COPD, or are a heavy smoker, you should discuss with your doctor whether treatment with a TNF blocker is appropriate for you.
- Caution should be used when treating the elderly because there is a higher incidence of infections in the elderly population.

Using other medicines with HYRIMOZ

Always tell your healthcare professional if you are using any other medicine (This includes complementary or traditional medicines).

HYRIMOZ can be used together with methotrexate or certain disease-modifying anti-rheumatic agents (sulfasalazine, hydroxychloroquine, leflunomide and injectable gold preparations), steroids or pain medications including non-steroidal anti-inflammatory drugs.

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

Using HYRIMOZ with food and drink

Since HYRIMOZ is given subcutaneously, food and drink should not affect HYRIMOZ.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist, or other health care professional for advice before usingHYRIMOZ.

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.

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 HYRIMOZ during pregnancy compared with mothers with the same disease who did not receive HYRIMOZ.
HYRIMOZ can be used during breastfeeding.

If you receive HYRIMOZ during your pregnancy, your baby may have a higher risk for getting an infection. It is important that you tell your baby's doctors and other healthcare professionals about your HYRIMOZ use during pregnancy before the baby receives any vaccine.

Driving and using machines

HYRIMOZ may have a small effect on your ability to drive, cycle or use machines. Room spinning sensation and vision disturbances may occur after using HYRIMOZ.

HYRIMOZ contains

Adipic acid, citric acid monohydrate, hydrochloric acid (for pH adjustment), mannitol, polysorbate 80, sodium chloride, sodium hydroxide (for pH adjustment), water for injections.

3. HOW TO USE HYRIMOZ:

Do not share medicines prescribed for you with any other person.
Always use HYRIMOZ exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

HYRIMOZ is injected under the skin (subcutaneous use).
Your doctor will determine and prescribe the appropriate dosage(s) according to your condition and other aspect of your treatment.

Adults:

The usual dose for adults with **rheumatoid arthritis**, **psoriatic arthritis** and **axial spondyloarthritis** including **ankylosing spondylitis** is 40 mg of HYRIMOZ given every other week as a single dose.

The recommended HYRIMOZ dose regimen for adult patients with **Crohn's disease** is 160 mg at week 0 (dose can be administered as four injections in one day or as two injections per day for two consecutive days), 80 mg at week 2, and followed 2 weeks later by maintenance dose of 40 mg every other week via subcutaneous injection.

The recommended HYRIMOZ dose regimen for adult patients with **ulcerative colitis** is 160 mg at Week 0 (dose can be administered as four injections in one day or as two injections per day for two consecutive days) and 80 mg at Week 2, and thereafter 40 mg every other week. Depending on your response, your doctor may increase the dose to 40 mg every week.

The usual dose for adults with **psoriasis** is an initial dose of 80 mg, followed by 40 mg given every other week starting one week after the initial dose. Depending on your response, your doctor may increase the dose to 40 mg every week.

***Adults with Hidradenitis Suppurativa*:**

The usual dose regimen for **hidradenitis suppurativa** is an initial **dose of 160 mg** (dose can be administered as four injections in one day or as two injections per day for two consecutive days), followed by 80 mg (as two injections on the same day) two weeks later. After two further weeks, continue with a dose of 40 mg every week. It is recommended that you use an antiseptic wash daily on the affected areas.

***Uveitis*:**

The recommended dose of HYRIMOZ for adult patients with uveitis is an initial dose of 80 mg, followed by 40 mg given every other week starting one week after the initial dose. HYRIMOZ can be used alone or in combination with corticosteroids.

Paediatrics:

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

***Paediatric Uveitis*:**

The recommended dose of HYRIMOZ for paediatric patients 2 years of age and older with chronic non-infectious uveitis is based on body weight (Table 4). HYRIMOZ is administered via subcutaneous injection. HYRIMOZ may be used in combination with methotrexate or other non-biologic immunomodulatory agents based on clinical judgement.

Table 4: HYRIMOZ Dose by Weight for Patients with Paediatric Uveitis

Age and body weight	**How much and how often to take?**
Children and adolescents from 2 years of age weighing 30 kg or more	40 mg every other week

You should continue to inject HYRIMOZ for as long as instructed by your doctor.

In rheumatoid arthritis and juvenile idiopathic arthritis, methotrexate is continued while using HYRIMOZ. If your doctor determines that methotrexate is inappropriate, HYRIMOZ can be given alone.

If you have rheumatoid arthritis and you do not receive methotrexate with your HYRIMOZ therapy, your doctor may decide to give 40 mg of HYRIMOZ every week.

Instructions for preparing and giving an injection of HYRIMOZ:

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 preparing and giving an injection of 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.

PRE-FILLED SYRINGE:

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

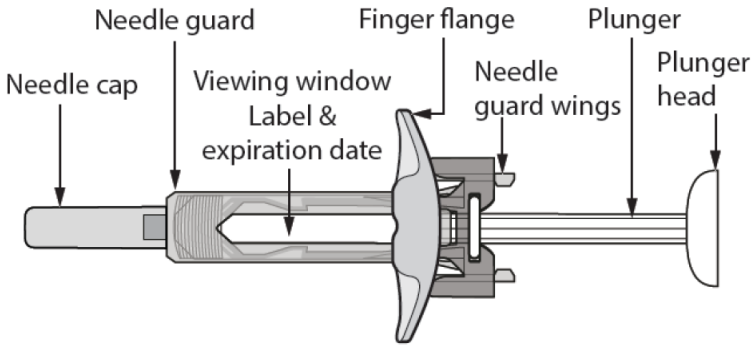


Figure A: Hyrimoz pre-filled syringe with needle guard and add-on finger flange

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.
- **Do not shake** the syringe.
- 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.**

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 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

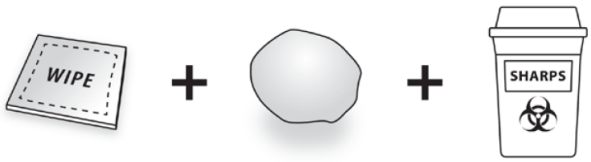


Figure B: items not included in the carton

Before your injection

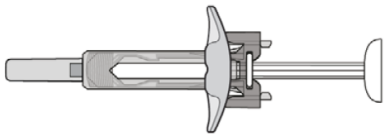


Figure C: needle guard is not activated – the syringe is ready for use

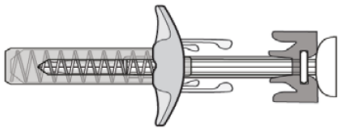


Figure D: needle guard is activated – do not use

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

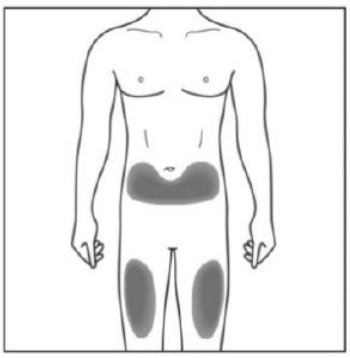
- In this configuration the needle guard is **ACTIVATED.**
- **DO NOT USE** the syringe (see *Figure D*).

Preparing the syringe

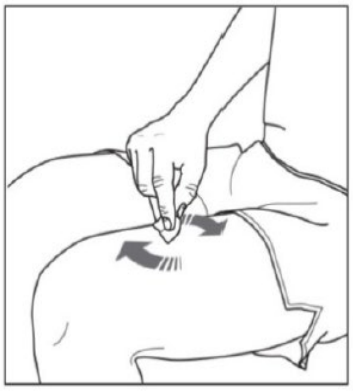
- For a more comfortable injection, take the blister containing the syringe out of the refrigerator and leave it unopened on your work surface for about 15 to 30 minutes so that it reaches room temperature.
- Take the syringe out of the blister
- Look through the viewing window. The solution should be colourless to 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 appearance of the solution, then contact your healthcare provider 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 the syringe if the expiration date has passed.

Contact your healthcare provider if the syringe fails any of the above-mentioned checks.

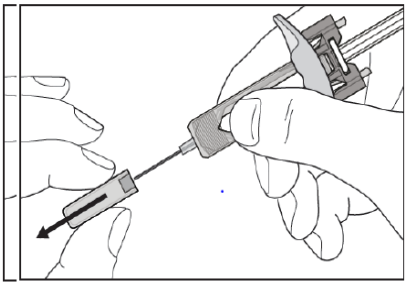
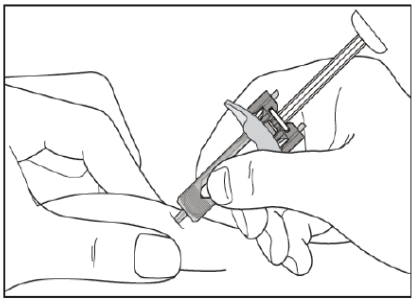
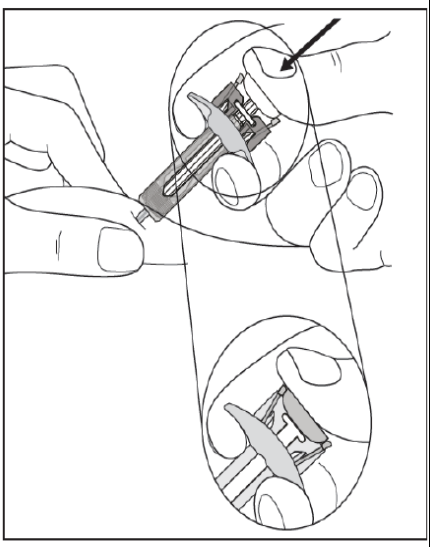
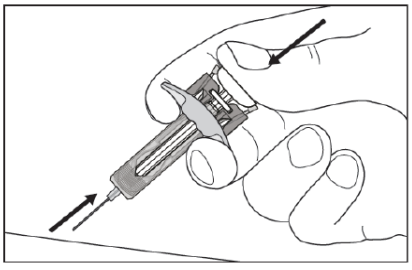
1a. Choosing your injection site:

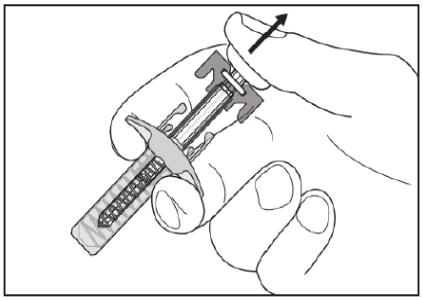
• the recommended injection site is the front of your thighs. You may also use the lower abdomen, but not the area 5 cm around your naval (belly button) (see *Figure E*). • Choose a different site each time you give yourself an injection. • Do not inject into areas where the skin is tender, bruised, 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*

2a. 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*

3a. 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*

4a. Throwing away supplies

- The HYRIMOZ syringe should **NEVER** be re-used. **NEVER** recap a needle.
- After injecting HYRIMOZ, immediately throw away the used syringe in a special container as instructed by your doctor, nurse, or pharmacist.

PRE-FILLED PEN

Your HYRIMOZ single-use pre-filled pen

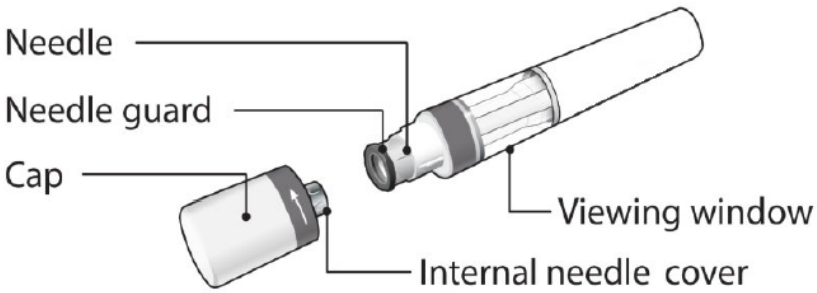


Figure A: Hyrimoz pen parts

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.
- **do not shake** the pen
- 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.**

What do you need for your injection?

Place the following items on a clean, flat surface.

Included in your carton is:

- Hyrimoz pre-filled 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

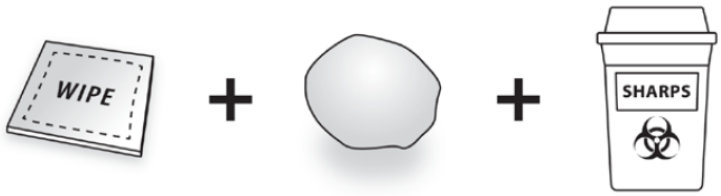


Figure B: items not included in the carton

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 colourless to slightly yellowish. 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.

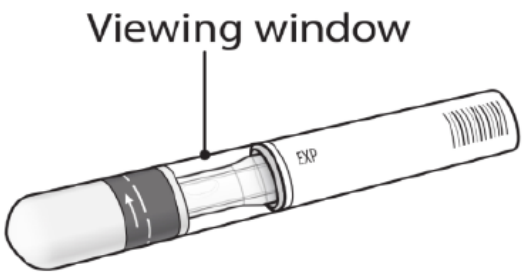


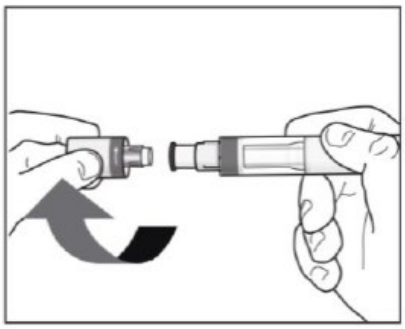
Figure C: Safety Checks before injection

- 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.

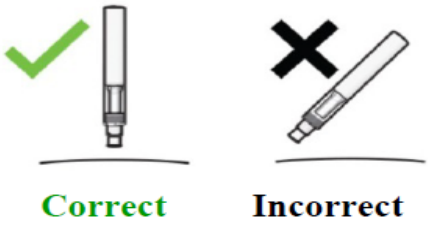
Contact your pharmacist if the pen fails any of the above-mentioned checks.

Follow Steps 1a and 2a above for information on choosing and cleaning your injection site, then:

3b. Remove 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*

4b. Holding the pen:

• Hold your pen at 90 degrees to the cleaned injection site (see *Figure G*).  	 *Figure G: hold your pen*

Your injection:

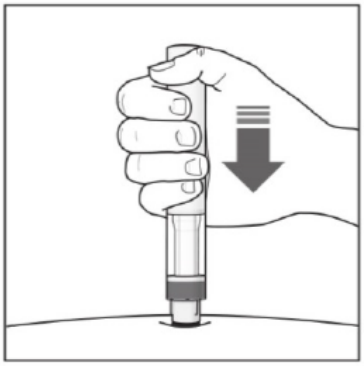
You must read this before injecting

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.

5b. 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*

6b. Completing your injection:

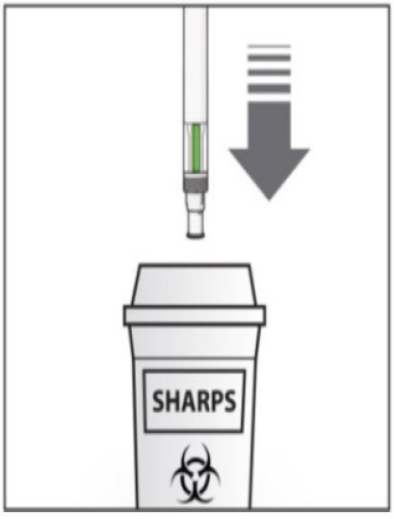
• Listen for the **2nd click**. This indicates the injection is **almost** complete. • Check the **green indicator** fills the window and has stopped moving (see *Figure I*). • The pen can now be removed.	 *Figure I: complete your injection*

After your injection

7b. 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*

8b. 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. The measures will help protect the environment. Any unused product or waste material should be disposed of in accordance with local requirements.	

Keep this container out of reach and sight of children.

If you use more HYRIMOZ than you should:

If you accidently inject HYRIMOZ more frequently than you should, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to use HYRIMOZ:

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

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

If you stop using HYRIMOZ:

Do not stop using HYRIMOZ even if you are feeling well unless your doctor tells you.

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

4. Possible side effects

HYRIMOZ can have side effects.

Not all side effects reported for HYRIMOZ are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using HYRIMOZ, please consult your health care provider for advice.

Seek medical attention urgently, if you notice any of the following signs of allergic reaction or heart failure:

- severe rash, hives;
- swollen face, hands, feet;
- trouble breathing, swallowing;
- shortness of breath with 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 and symptoms of infection such as fever, feeling sick, wounds, dental problems, burning on urination, feeling weak or tired or coughing;

- symptoms of nerve problems such as tingling, numbness, double vision or arm or leg weakness;
- signs of skin cancer such as bump or open sore that doesn'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:

Frequent side effects (may affect more than 1 in 10 people)

- injection site reactions (including pain, swelling, redness or itching);
- respiratory tract infections (including cold, runny nose, sinus infection, pneumonia);
- headache;
- abdominal (belly) pain:
- nausea (feeling an urge to vomit or being sick to your stomach) and vomiting (to throw up).
- rash (an area of the skin that has changes in texture or colour and may look inflamed or irritated. The skin may be red, warm, scaly, bumpy, dry, itchy, swollen, or painful. It may also crack or blister);
- pain in the muscles.
- serious infections (including blood poisoning and influenza);
- intestinal infections (including gastroenteritis: inflammation of the lining of the stomach and intestines. The main symptoms include vomiting and diarrhoea. It is usually not serious in healthy people, but it can sometimes lead to dehydration or cause severe symptoms);
- skin infections (including cellulitis and shingles);
- ear infections;
- mouth infections (including tooth infections and cold sores);
- reproductive tract infections;
- urinary tract infection;
- fungal infections;
- joint infections;
- benign tumours;
- skin cancer;
- allergic reactions (including seasonal allergy);

- dehydration;
- mood swings (including depression);
- anxiety (a feeling of fear, dread, and uneasiness);
- difficulty sleeping;
- sensation disorders such as tingling, prickling or numbness;
- migraine (a migraine is a type of headache. It may occur with symptoms such as nausea, vomiting, or sensitivity to light and sound. In most people, a throbbing pain is felt only on one side of the head);
- symptoms of nerve root compression (including lower back pain and leg pain);
- vision disturbances;
- eye inflammation;
- inflammation of the eye lid and eye swelling;
- vertigo (sensation of room spinning);
- sensation of heart beating rapidly;
- high blood pressure;
- flushing;
- haematoma (a solid swelling with clotted blood);
- 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 (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.

Less Frequent side effects (may affect up to 1 in 100 people)

- unusual infections (which include tuberculosis and other infections) that occur when resistance to disease is lowered;
- neurological infections (including viral meningitis);
- eye infections;
- bacterial infections;
- diverticulitis (inflammation and infection of the large intestine);
- cancer, including cancer that affects the lymph system (lymphoma) and melanoma (a type of skin cancer);
- immune disorders that could affect the lungs, skin and lymph nodes (most commonly as a condition called sarcoidosis);
- vasculitis (inflammation of blood vessels);
- tremor;
- neuropathy (nerve damage);
- stroke;
- double vision;
- 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;
- gallbladder inflammation, gallbladder stones;
- fatty liver (build-up of fat in liver cells);
- night sweats;
- scar;
- abnormal muscle breakdown;
- systemic lupus erythematosus (an immune disorder including inflammation of skin, heart, lung, joints and other organ systems);
- sleep interruptions;
- impotence (being unable to engage in sexual intercourse because of inability to have and maintain an erection);
- inflammations;
- leukaemia (cancer affecting the blood and bone marrow);
- severe allergic reaction with shock;
- multiple sclerosis;
- nerve disorders (such as inflammation of the optic nerve to the eye, and Guillain-Barré syndrome, a condition that may cause muscle weakness, abnormal sensations, tingling in the arms and upper body);
- heart stops pumping;
- pulmonary fibrosis (scarring of the lung);
- intestinal perforation (hole in the wall of the gut);
- hepatitis (liver inflammation);
- reactivation of hepatitis B infection;

- autoimmune hepatitis (inflammation of the liver caused by the body's own immune system);
- cutaneous vasculitis (inflammation of blood vessels in the skin);
- Stevens-Johnson syndrome (life-threatening reaction with flu-like symptoms and blistering rash);
- facial oedema (swelling) associated with allergic reactions;
- erythema multiforme (inflammatory skin rash);
- lupus-like syndrome;
- angioedema (localised swelling of the skin);
- lichenoid skin reaction (itchy reddish-purple skin rash)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Frequency Unknown (frequency cannot be estimated from available data)

- hepatosplenic T-cell lymphoma (a rare blood cancer that is often fatal);
- Merkel cell carcinoma (a type of 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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of HYRIMOZ. Suspected side effects can also be reported directly to the Holder of Certificate of Registration HCR via the website: https://pvi1j.solutions.iqvia.com or the e-mail address, adverse.event.sac@sandoz.com.

5. How to store HYRIMOZ:

- Store in a refrigerator (2 °C – 8 °C). Do not freeze. Do not shake.
- Keep the pre-filled syringe or pen in the outer carton in order to protect from light.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Do not use after the expiry date printed on the label or carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g., toilets).

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 or pen **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 or pen is first removed from the refrigerator, and the date after which it should be discarded.

6. Contents of the pack and other information

What HYRIMOZ contains

The active substance is adalimumab. Each pre-filled pen and each pre-filled syringe contains 40 mg of adalimumab in 0,8 mL of solution.

The other ingredients are adipic acid, citric acid monohydrate, hydrochloric acid (for pH adjustment), mannitol, polysorbate 80, sodium chloride, sodium hydroxide (for pH adjustment), water for injection.

What HYRIMOZ looks like and contents of the pack

Hyrimoz 40 mg solution for injection in pre-filled pen or pre-filled syringe is supplied as a 0,8 mL colourless to slightly yellowish solution.

Pre-filled syringe: HYRIMOZ is supplied in a single-use clear type I glass syringe with a grey rubber stopper and a stainless-steel needle with a needle guard with finger flange, rubber needle cap and plastic plunger, containing 0,8 mL of solution.

Pre-filled pen: HYRIMOZ is supplied in a single-use pre-filled syringe assembled into a triangular-shaped pen with transparent window and label. The syringe inside the pen is made of type I glass with

a stainless-steel needle and an inner rubber needle cap, and a grey rubber stopper, containing 0,8 mL of solution.

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

Cartons contain 1 and 2 pre-filled pens.

Cartons contain 1 and 2 pre-filled syringes in a blister.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

Magwa Crescent West

Waterfall City

Jukskei View

2090

[1]Company Reg. No.: 1990/001979/07

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