

**Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986**  
**This medicine is dispensed with a doctor's prescription only**

## Hyrimoz®

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

**Solution for subcutaneous injection**

**Name and quantity of active ingredient:** adalimumab 40 mg in 0.8 ml

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

**Read the entire leaflet carefully before you start using this medicine.**

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

### Please note

**It is important that, every time you get this medicine at the pharmacy, you check that you have been given the same medicine that your specialist prescribed you.**

**If the medicine you are given looks different from what you usually get, or if the instructions for use have changed, please consult your pharmacist immediately to make sure you received the correct medicine. Only your specialist can switch your medicine or change the dosage of a medicine that contains adalimumab.**

**Please check that the medicine that your specialist prescribed you has the same brand name as the medicine you got from the pharmacist.**

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

### 1. What is Hyrimoz intended for?

**Hyrimoz is intended for the treatment of:**

**Rheumatoid arthritis**

Hyrimoz in combination with methotrexate is given in the following conditions:

- the treatment of moderate to severe, active rheumatoid arthritis in adult patients when treatment with disease-modifying anti-rheumatic drugs (DMARDs) including methotrexate has not helped.
- the treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate.
- Hyrimoz can be given as single-medication treatment in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate.

**Axial spondyloarthritis**

Hyrimoz is intended for treatment of adults with severe active ankylosing spondylitis when standard therapy has not helped.

- Hyrimoz is indicated for the treatment of adults with severe axial spondyloarthritis without radiographic evidence of the disease, but with signs of inflammation by radiological/laboratory tests (including MRI and serum CRP levels), when treatment with non steroidal anti-inflammatory drugs (NSAIDs) has not helped or is inappropriate.

**Psoiritic arthritis**

Hyrimoz is indicated for the treatment of active and progressive psoriatic arthritis in adults when previous disease-modifying anti-rheumatic drug therapy has not helped.

**Plaque psoriasis**

Hyrimoz is indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy.

**Hidradenitis suppurativa (HS)**

Hyrimoz is indicated for the treatment of moderate to severe hidradenitis suppurativa in adults with an inadequate response to conventional HS therapy.

**Crohn's disease**

Hyrimoz is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease when standard therapy has not helped. Hyrimoz is indicated for reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are no longer able to take medicine that contains infliximab.

**Ulcerative colitis**

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

**Uveitis**

Hyrimoz is indicated for the treatment of non-infectious intermediate, posterior, and pan uveitis in adult patients when corticosteroid therapy has not helped or is inappropriate.

**Intestinal Behcet's disease**

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

**Therapeutic group:**

TNF-α blocker and selective immunosuppressant.

### 2. Before using Hyrimoz

**Do not use Hyrimoz if:**

- you are allergic (hypersensitive) to the active ingredient adalimumab or to any of the other ingredients in Hyrimoz (see also section 6).
- you have a severe infection, including tuberculosis, blood poisoning (sepsis) or other opportunistic infections (unusual infections associated with a weakened immune system). It is important that you tell your doctor if you have symptoms of infections, such as fever, wounds, feeling tired, and dental problems (see also under 'Special warnings about using Hyrimoz').
- you have moderate or severe heart failure. It is important that you tell your doctor if you have had or have a serious heart condition (see also under 'Special warnings about using Hyrimoz').

**Special warnings about using Hyrimoz**

Talk to your doctor or pharmacist before using Hyrimoz.

**Allergic reaction**

- If you have allergic reactions with symptoms such as chest tightness, wheezing, dizziness, swelling or rash, stop taking Hyrimoz and contact your doctor immediately, since in rare cases, these reactions can be life-threatening.

**Infections**

- If you have an infection, including long-term or localized infection (for example a leg ulcer), consult your doctor before starting Hyrimoz. If you are unsure, contact your doctor.
- You might get infections more easily while you are receiving Hyrimoz treatment. This risk may increase if your lung function is reduced. These infections may be more serious and include tuberculosis, infections caused by viruses, fungi, parasites or bacteria, or other unusual infectious organisms and blood poisoning (sepsis). In rare cases, these infections may be life-threatening. It is important to tell your doctor if you get symptoms such as fever, wounds, feeling tired or dental problems. Your doctor may decide to temporarily stop your Hyrimoz treatment.

**Tuberculosis**

- As cases of tuberculosis have been reported in patients treated with adalimumab, your doctor will check you for signs and symptoms of tuberculosis before starting Hyrimoz. This will include a thorough medical evaluation including your medical history and suitable screening tests (for example chest X-ray and a tuberculin test for tuberculosis). The conduct and results of these tests will be recorded on **your Patient Safety Information Card**. It is very important that you tell your doctor if you have ever had tuberculosis, or if you have been in close contact with someone who has tuberculosis. Tuberculosis can develop during therapy even if you have had preventative treatment. If symptoms of tuberculosis (persistent cough, weight loss, listlessness, mild fever) or any other infection appears during or after therapy tell your doctor immediately.

**Travel / recurrent infection**

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

**Hepatitis B virus**

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

**Age over 65 years**

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

**Surgery or dental procedures**

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

**Demyelinating disease**

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

**Vaccine**

- Certain vaccines contain living but weakened forms of disease-causing bacteria or viruses and must not be given during treatment with Hyrimoz. Check with your doctor before you receive any vaccines. If you receive Hyrimoz while you are pregnant, your baby may be at higher risk of getting an infection for up to about 5 months after the last dose you received during pregnancy. It is important that you tell your baby's doctors and other health care professionals about your Hyrimoz use during your pregnancy so they can decide when your baby should receive any vaccine.

**Heart failure**

- It is important to tell your doctor if you have had or have a serious heart condition. If you have mild heart failure and you are being treated with Hyrimoz, your heart failure status must

be closely monitored. If you develop new or worsening symptoms of heart failure (such as shortness of breath, or swelling of your feet), you must contact your doctor immediately.

**Fever, bruising, bleeding or looking pale**

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

**Cancer**

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

**Autoimmune disease**

- On rare occasions, treatment with Hyrimoz could result in lupus-like syndrome. Contact your doctor, if symptoms such as persistent unexplained rash, fever, joint pain or tiredness occur.

**Smoking**

If you are a heavy smoker, discuss with your doctor whether treatment with a TNFα blocker is appropriate for you.

**Children and adolescents**

This medicine is not intended for children and adolescents under 18 years old.

**Other medicines and Hyrimoz**

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

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

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

**Pregnancy and breastfeeding**

**Pregnancy**

- You should consider the use of adequate contraception to prevent pregnancy and continue its use for at least 5 months after the last Hyrimoz treatment.
- If you are pregnant, think you may be pregnant, or are planning to have a baby, ask your doctor for advice before taking Hyrimoz.
- Hyrimoz should only be used during a pregnancy if needed.
- According to a pregnancy study, there was no higher risk of birth defects when the mother had received adalimumab during pregnancy compared with mothers with the same disease who did not receive adalimumab.
- If you receive Hyrimoz during your pregnancy, your baby may have a higher risk of getting an infection.

- It is important that you tell your baby's doctors and other health care professionals at your clinic and well-baby clinic that you took Hyrimoz during your pregnancy before the baby receives any vaccine (for more information on vaccines see the 'Special warnings about using Hyrimoz' section).

**Breastfeeding -**

- Hyrimoz can be taken during breastfeeding.

**Driving and using machines**

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

**Important information about some of the ingredients in Hyrimoz**
Hyrimoz contains less than 1 mmol of sodium (23 mg) per 0.8 ml dose, that is to say essentially 'sodium-free'.

### 3. How to use Hyrimoz?

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

Do not use a pre-filled syringe that contains 40 mg of the active substance adalimumab if you have been prescribed a dose that is not 40 mg.

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

**Do not exceed the recommended dose.**

**How to use this medicine:**

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

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

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

Adhere to the treatment as recommended by your doctor.

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

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

**Do not take medicines in the dark! Check the label and the dose every time you take medicine. Wear glasses if you need them.**

**If you have any further questions about using this medicine, consult your doctor or pharmacist.**

#### 4. Side effects

Like with all medicines, using Hyrimoz may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Most side effects are mild to moderate. However, some may be serious and require treatment. Side effects may occur up to 4 months or more after the last Hyrimoz injection.

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

- severe rash, hives;
- swelling of the face, throat, hands, or feet;
- trouble breathing, trouble swallowing;
- shortness of breath with exertion or upon lying down, or swelling of the feet.

**Tell your doctor as soon as possible, if you notice any of the following:**

• signs and symptoms of infection such as fever, nausea, wounds, dental problems, burning on urination, feeling weak or tired or coughing;

- symptoms of nerve problems such as tingling, numbness, double vision or arm or leg weakness;
- signs of skin cancer such as a bump or an open sore that does not heal;
- signs and symptoms suggestive of blood disorders such as persistent fever, bruising, bleeding, paleness.

**Additional side effects**

**Very common 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 and vomiting;
- rash;
- pain in the muscles.
- Common side effects (may affect 1-10 in 100 people):**
  - serious infections (including blood poisoning and influenza);
  - intestinal infections (including gastroenteritis);
  - skin infections (including cellulitis and shingles);
  - ear infections;
  - mouth infections (including tooth infections and cold sores);
  - reproductive tract infections;
  - urinary tract infections;
  - fungal infections;
  - joint infections;
  - benign tumors;
  - skin cancer;
  - allergic reactions (including seasonal allergy);
  - dehydration;
  - mood swings (including depression);
  - anxiety;
  - difficulty sleeping;
  - sensation disorders such as tingling, prickling or numbness;
  - migraine;
  - symptoms of nerve root compression (including low back pain and leg pain);
  - vision disturbances;
  - eye inflammation;
  - inflammation of the eye lid and eye swelling;
  - infection of spinning (vertigo);
  - sensation of heart beating rapidly;
  - high blood pressure;
  - flushing;
  - hematoma (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;

• edema (a build-up of fluid in the body which causes the affected tissue to swell);

• fever;

• reduction in blood platelets which increases risk of bleeding or bruising;

• impaired healing.

**Uncommon side effects (may affect 1-10 in 1,000 people):**

- unusual/opportunistic infections (which include tuberculosis and other infections) that occur when resistance to disease is lowered;
- infections of the nervous system (including viral meningitis);
- eye infections;
- bacterial infections;
- diverticulitis (inflammation and infection of the large intestine);
- cancer, including cancer that affects the lymph system (lymphoma) and melanoma (a type of skin cancer);

• immune disorders that could affect the lungs, skin and lymph nodes (most commonly as a condition called sarcoidosis);

• inflammation of blood vessels (vasculitis);

• tremor;

• 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 space surrounding the lungs);

• inflammation of the pancreas which causes severe pain in the abdomen and back;

• difficulty in swallowing;

• facial edema (swelling);

• gallbladder inflammation, gallbladder stones;

• fatty liver (build-up of fat in liver cells);

• night sweats;

• scarring;

• muscle breakdown;

• systemic lupus erythematosus (an immune disorder including inflammation of skin, heart, lung, joints and other organs);

• sleep interruptions;

• impotence;

• inflammations.

**Rare side effects (may affect 1-10 in 10,000 people):**

• leukemia (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;

• scarring of the lung (pulmonary fibrosis);

• intestinal perforation (hole in the wall of the gut);

• liver inflammation (hepatitis);

• reactivation of viral hepatitis B infection;

• autoimmune hepatitis (inflammation of the liver caused by the body's own immune system);

• inflammation of blood vessels in the skin;

• Stevens-Johnson syndrome (life-threatening reaction with flu-like symptoms and blistering rash);

• facial edema (swelling) associated with allergic reactions;

• erythema multiforme (inflammatory skin rash);

• lupus-like syndrome;

• angioedema (localized swelling of the skin);

• lichenoid skin reaction (itchy reddish-purple skin rash).

**Side effects of unknown frequency (the frequency of these effects has not been established yet):**

• hepatosplenic T-cell lymphoma (a rare blood cancer that is often fatal);

• Merkel cell carcinoma (a type of skin cancer);

• Kaposi's sarcoma (a rare cancer related to infection with human herpes virus 8. Kaposi's sarcoma most commonly appears as purple lesions on the skin);

• liver failure;

• worsening of a condition called dermatomyositis (seen as a skin rash accompanying muscle weakness).

**Some side effects observed with adalimumab do not have symptoms and can only be discovered through blood tests. These include:**

**Very common side effects (may affect more than 1 in 10 people):**

- low blood measurements for white blood cells;
- low blood measurements for red blood cells;
- increased lipids in the blood;
- raised liver enzymes.

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

**Uncommon side effects (may affect 1-10 in 1,000 people):**

- high measurement for bilirubin (blood test for liver function).

**Rare side effects (may affect 1-10 in 10,000 people):**

- low blood measurements for white blood cells, red blood cells, and platelets.

**If you experience any side effect, if any side effect gets worse or you experience a side effect not mentioned in this leaflet, or if there is any change in how you feel in general, consult your doctor immediately.**