Package leaflet: Information for the patient

Hyrimoz 40 mg solution for injection in pre-filled pen
adalimumab
40 mg/0.8 ml

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- Your doctor will also give you a **Patient Reminder Card**, which contains important safety information that you need to be aware of before you are given Hyrimoz and during treatment with Hyrimoz. Keep this **Patient Reminder Card** with you during your treatment and for 4 months after your (or your child's) last injection of Hyrimoz.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get 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

Hyrimoz contains the active substance adalimumab, a medicine that acts on your body's immune (defence) system.

Hyrimoz is intended for the treatment of the following inflammatory diseases:
- rheumatoid arthritis,
- polyarticular juvenile idiopathic arthritis,
- enthesitis-related arthritis,
- ankylosing spondylitis,
- axial spondyloarthritis without radiographic evidence of ankylosing spondylitis,
- psoriatic arthritis,
- psoriasis,
- hidradenitis suppurativa,
- Crohn's disease,
- ulcerative colitis and
- non-infectious uveitis.

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

The target of adalimumab is another protein called tumour necrosis factor (TNFα), which is present at increased levels in the inflammatory diseases listed above. By attaching to TNFα, Hyrimoz blocks its action and reduces the inflammation in these diseases.

Rheumatoid arthritis

Rheumatoid arthritis is an inflammatory disease of the joints.

Hyrimoz is used to treat rheumatoid arthritis in adults. If you have moderate to severe active rheumatoid arthritis, you may first be given other disease-modifying medicines, such as methotrexate. If these medicines do not work well enough, you will be given Hyrimoz to treat your rheumatoid arthritis.

Hyrimoz can also be used to treat severe, active and progressive rheumatoid arthritis without previous methotrexate treatment.

Hyrimoz can slow down the damage to the cartilage and bone of the joints caused by the disease and improve physical function.

Usually, Hyrimoz is used with methotrexate. If your doctor considers that methotrexate is inappropriate, Hyrimoz can be given alone.

Polyarticular juvenile idiopathic arthritis and enthesitis-related arthritis

Polyarticular juvenile idiopathic arthritis and enthesitis-related arthritis are inflammatory diseases of the joints that usually first appear in childhood.

Hyrimoz is used to treat polyarticular juvenile idiopathic arthritis in children and adolescents aged 2 to 17 years and enthesitis-related arthritis in children and adolescents aged 6 to 17 years. Patients may first be given other disease-modifying medicines, such as methotrexate. If these medicines do not work well enough, patients will be given Hyrimoz to treat their polyarticular juvenile idiopathic arthritis or enthesitis-related arthritis.

Ankylosing spondylitis and axial spondyloarthritis without radiographic evidence of ankylosing spondylitis

Ankylosing spondylitis and axial spondyloarthritis without radiographic evidence of ankylosing spondylitis, are inflammatory diseases of the spine.

Hyrimoz is used in adults to treat these conditions. If you have ankylosing spondylitis or axial spondyloarthritis without radiographic evidence of ankylosing spondylitis, you will first be given other medicines. If these medicines do not work well enough, you will be given Hyrimoz to reduce the signs and symptoms of your disease.

Plaque psoriasis in adults and children

Plaque psoriasis is an inflammatory 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 moderate to severe plaque psoriasis in adults. Hyrimoz is also used to treat severe plaque psoriasis in children and adolescents aged 4 to 17 years for whom medicines applied to the skin and treatment with UV light have either not worked very well or are not suitable.

Psoriatic arthritis

Psoriatic arthritis is an inflammatory disease of the joints associated with psoriasis.

Hyrimoz is used to treat psoriatic arthritis in adults. Hyrimoz can slow down the damage to the

cartilage and bone of the joints caused by the disease and improve physical function.

Hidradenitis suppurativa in adults and adolescents

Hidradenitis suppurativa (sometimes called acne inversa) is a long-term 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 and adolescents from 12 years of age. Hyrimoz can reduce the number of nodules and abscesses you have, and the pain that is often associated with the disease. You may first be given other medicines. If these medicines do not work well enough, you will be given Hyrimoz.

Crohn's disease in adults and children

Crohn's disease is an inflammatory disease of the gut.

Hyrimoz is used to treat Crohn's disease in adults and children aged 6 to 17 years. If you have Crohn's disease you will first be given other medicines. If you do not respond well enough to these medicines, you will be given Hyrimoz to reduce the signs and symptoms of your Crohn's disease.

Ulcerative colitis in adults and children

Ulcerative colitis is an inflammatory disease of the large intestine.

Hyrimoz is used to treat moderate to severe ulcerative colitis in adults children aged 6 to 17 years. If you have ulcerative colitis you may first be given other medicines. If these medicines do not work well enough, you will be given Hyrimoz to reduce the signs and symptoms of your disease.

Non-infectious uveitis in adults and children

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

Hyrimoz is used to treat
- adults with non-infectious uveitis with inflammation affecting the back of the eye.
- children from 2 years of age with chronic non-infectious uveitis 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 to adalimumab or any of the other ingredients of this medicine (listed in section 6).
- if you have a severe infection, including tuberculosis, sepsis (blood poisoning) 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, e.g. fever, wounds, feeling tired, dental problems (see "Warnings and precautions").
- 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 "Warnings and precautions").

Warnings and precautions

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, do not inject more Hyrimoz and contact your doctor immediately, since in rare cases, these reactions can be life-threatening.

Infection

- 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, 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 sepsis (blood poisoning).
- 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 recommend temporarily stopping Hyrimoz.

Tuberculosis (TB)

- 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 screening tests (for example chest X-ray and a tuberculin test). The conduct and results of these tests should be recorded on your Patient Reminder 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 had tuberculosis. Tuberculosis can develop during therapy even if you have had preventative treatment for tuberculosis. If symptoms of tuberculosis (persistent cough, weight loss, listlessness, mild fever), or any other infection appear 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. Adalimumab can reactivate HBV infection 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 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 infections, such as fever, wounds, feeling tired or dental problems.

Surgery or dental procedures

- If you are about to have surgery or dental procedures 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 should not be given during treatment with Hyrimoz in case they cause infections. Check with your doctor before you receive any vaccines. It is recommended that, if possible, children be given all the scheduled vaccinations for their age before they start treatment with Hyrimoz.

  If you receive Hyrimoz while you are pregnant, your baby may be at higher risk for getting an infection for up to about five 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 by your doctor. 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.

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. People 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 leukaemia (cancers that affect blood cells and bone marrow). If you take Hyrimoz the risk of getting lymphoma, leukaemia, 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.
- In addition cases of non-melanoma skin cancer have been observed in patients taking adalimumab. If new areas of damaged skin appear during or after treatment or if existing marks or areas of damage change appearance, tell your doctor.
- There have been cases of cancers, other than lymphoma, in patients with a specific type of lung disease called chronic obstructive pulmonary disease (COPD) treated with another

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

Autoimmune diseases

- 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.

Children and adolescents

- Do not give Hyrimoz to children with polyarticular juvenile idiopathic arthritis below the age of 2 years.
- Do not give Hyrimoz to children with paediatric plaque psoriasis or paediatric ulcerative colitis below the age of 4 years.
- Do not give Hyrimoz to children with paediatric Crohn's disease below the age of 6 years.
- Do not use the 40 mg pre-filled pen if doses other than 40 mg are recommended.

Other medicines and Hyrimoz

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

You should not take Hyrimoz with medicines containing the active substances anakinra or abatacept due to increased risk of serious infection. The combination of adalimumab as well as other TNF-antagonists and anakinra or abatacept is not recommended based upon the possible increased risk for infections, including serious infections and other potential pharmacological interactions. If you have questions, please ask your doctor.

Pregnancy and breast-feeding

- 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 this medicine.
- 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.
- Hyrimoz can be used during breast-feeding.
- 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 health care professionals about your Hyrimoz use during your pregnancy before the baby receives any vaccine (for more information on vaccines see the "Warnings and precautions" section).

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.

Hyrimoz contains sodium

This medicine 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

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

Hyrimoz is available as a 40 mg pen as well as 20 mg and 40 mg pre-filled syringes for patients to administer a full 20 mg or 40 mg dose.

Rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis or axial spondyloarthritis without radiographic evidence of ankylosing spondylitis		
Age and body weight	**How much and how often to take?**	**Notes**
Adults	40 mg every other week as a single dose	In rheumatoid 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 Hyrimoz every week or 80 mg every other week.

Polyarticular juvenile idiopathic arthritis		
Age and 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, 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 and 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

Psoriasis		
Age and body weight	**How much and how often to take?**	**Notes**
Adults	First dose of 80 mg (as two 40 mg injections in one day), followed by 40 mg given every other week starting one week after the first dose.	You should continue to inject Hyrimoz for as long as your doctor has told you. If this dose does not work well enough, your doctor may increase the dose to 40 mg every week or 80 mg every other week.

Plaque psoriasis		
Age and 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

Hidradenitis suppurativa		
Age and body weight	**How much and how often to take?**	**Notes**
Adults	First dose of 160 mg (as four 40 mg injections in one day or two 40 mg injections per day for two consecutive days), followed by an 80 mg dose (as two 40 mg injections on the same day) two weeks later. After two further weeks, continue with a dose of 40 mg every week or 80 mg every other week, as prescribed by your doctor.	It is recommended that you use an antiseptic wash daily on the affected areas.
Adolescents from 12 to 17 years of age weighing 30 kg or more	First dose of 80 mg (as two 40 mg injections in one day), followed by 40 mg every other week starting one week later.	If this dose does not work well enough, your doctor may increase the dose to 40 mg every week or 80 mg every other week. It is recommended that you use an antiseptic wash daily on the affected areas.

Crohn's disease		
Age and body weight	**How much and how often to take?**	**Notes**
Adults	First dose of 80 mg (as two 40 mg injections in one day), followed by 40 mg every other week starting two weeks later. If a faster response is required your doctor may prescribe a first dose of 160 mg (as four 40 mg injections in one day or two 40 mg injections per day for two consecutive days), followed by 80 mg (as two 40 mg injections in one day) two weeks later. Thereafter the usual dose is 40 mg every other week.	If this dose does not work well enough, your doctor may increase the dose to 40 mg every week or 80 mg every other week.

Paediatric Crohn's disease		
Age and body weight	**How much and how often to take?**	**Notes**
Children and adolescent from 6 to 17 years of age weighing 40 kg or more	First dose of 80 mg (as two 40 mg injections in one day), followed by 40 mg every other week starting two weeks later. If a faster response is required your doctor may prescribe a first dose of 160 mg (as four 40 mg injections in one day or two 40 mg injections per day for two consecutive days), followed by 80 mg (as two 40 mg injections in one day) two weeks later. Thereafter the usual dose is 40 mg every other week.	If this dose does not work well enough, your child's doctor may increase the dose 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 every other week starting two weeks later. If a faster response is required, your doctor may prescribe a first dose of 80 mg (as two 40 mg injections in one day), followed by 40 mg two weeks later. Thereafter the usual dose is 20 mg every other week.	If this dose does not work well enough, your child's doctor may increase the dose frequency to 20 mg every week.

Ulcerative colitis		
Age and body weight	**How much and how often to take?**	**Notes**
Adults	First dose is 160 mg (as four 40 mg injections in one day or as two 40 mg injections per day for two consecutive days), followed by 80 mg (as two 40 mg injections in one day) two weeks later. Thereafter, the usual dose is 40 mg every other week.	If this dose does not work well enough, your doctor may increase the dose to 40 mg every week or 80 mg every other week.

Paediatric ulcerative colitis		
Age and body weight	**How much and how often to take?**	**Notes**
Children and adolescents from 6 years of age weighing 40 kg or more	First dose is 160 mg (as four 40 mg injections in one day or two 40 mg injections per day for two consecutive days) initially, followed by 80 mg (as two 40 mg injections in one day) two weeks later. Thereafter the usual dose is 80 mg every other week. (as two 40 mg injections in one day)	Patients who turn 18 years of age while on 80 mg every other week, should continue their prescribed dose
Children and adolescents from 6 years of age weighing less than 40 kg	First dose is 80 mg (as two 40 mg injections in one day) initially followed by 40 mg (as one 40 mg injection) two weeks later. Thereafter, the usual dose is 40 mg every other week.	Patients who turn 18 years of age while on 40 mg every other week, should continue their prescribed dose.

Non-infectious uveitis		
Age and body weight	**How much and how often to take?**	**Notes**
Adults	First dose of 80 mg (as two 40 mg injections), followed by 40 mg every other week starting one week after the first dose.	In non-infectious uveitis, corticosteroids or other medicines that influence the immune system may be continued while using Hyrimoz. Hyrimoz can also be given alone. You should continue to inject Hyrimoz for as long as your doctor has told you.
Children and adolescents from 2 years of age weighing 30 kg or more	40 mg every other week with methotrexate	Your doctor may also prescribe a first dose of 80 mg which may be administered

		one week prior to the start of the usual dose.
Children and adolescents from 2 years of age weighing less than 30 kg	20 mg every other week with methotrexate	Your doctor may also prescribe a first dose of 40 mg which may be administered one week prior to the start of the usual dose.

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 you should, call your doctor or pharmacist and explain that you have taken more than required. Always take the outer carton of medicine with you, even if it is empty.

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 stop using Hyrimoz

The decision to stop using Hyrimoz should be discussed with your doctor. Your 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 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;
- swollen face, hands, feet;
- trouble breathing, 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, 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 a 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:

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 (belly) pain;
- nausea and vomiting;
- rash;
- pain in the muscles.

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;
- 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;
- 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;
- 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.

Uncommon (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;
- facial oedema (swelling);
- 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;
- 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 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).

Not known (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 skin cancer);
- Kaposi’s sarcoma, a rare cancer related to infection with human herpes virus 8. Kaposi’s sarcoma most commonly appears as purple lesions on the skin;
- liver failure;
- worsening of a condition called dermatomyositis (seen as a skin rash accompanying muscle weakness).
- weight gain (for most patients, the weight gain was small)

Some side effects observed with adalimumab 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;
- raised 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)

- raised 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 you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects, you can help provide more information on the safety of this medicine.

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 pen 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 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 pen 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 pen contains 40 mg of adalimumab in 0.8 ml of solution.
- The other ingredients are adipic acid, citric acid monohydrate, sodium chloride, mannitol (E 421) , polysorbate 80 (E 433), hydrochloric acid (E 507), sodium hydroxide (E 524) and water for injections (see section 2 “Hyrimoz contains sodium)).

What Hyrimoz looks like and contents of the pack

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.

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

29 gauge needle and an inner rubber needle cap (thermoplastic elastomer), containing 0.8 ml of solution.

Cartons contain 1 and 2 pre-filled pens of Hyrimoz.
Multipack cartons contain 6 (3 packs of 2) pre-filled pens of Hyrimoz.

Not all pack sizes may be marketed.
Hyrimoz is available as a pre-filled syringe and a pre-filled pen.

Marketing Authorisation Holder

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Manufacturer

Sandoz GmbH Schaftenau
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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This leaflet was last revised in

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.

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 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 pen

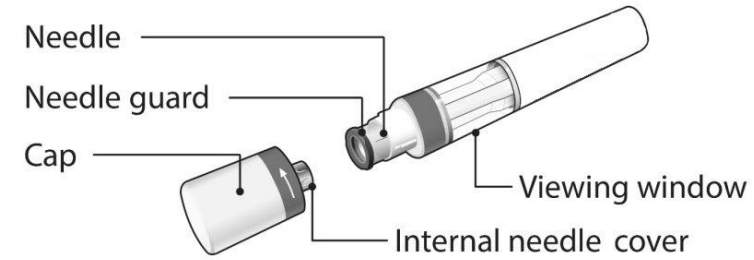


Figure A: Hyrimoz pen parts

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.
- 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. 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:

- 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

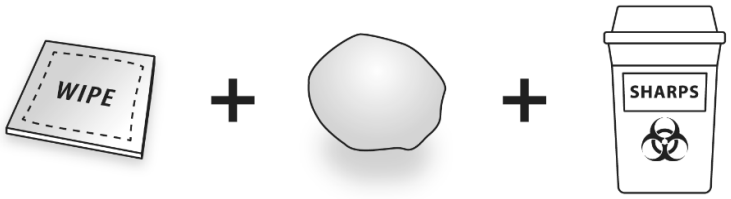


Figure B: items not included in the carton

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 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.

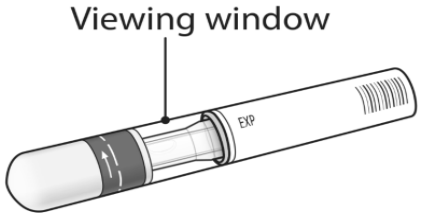


Figure C: Safety Checks before injection

- Look at the expiry date (EXP) on your pen. Do not use your pen if the expiry 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 5 cm 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.

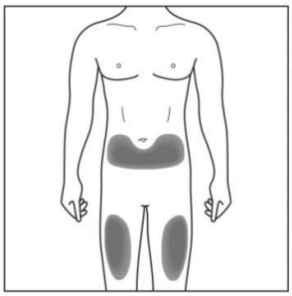


Figure D: choose your injection site

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.

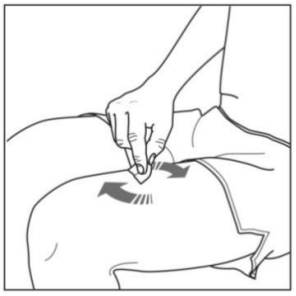


Figure E: clean your injection site

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.

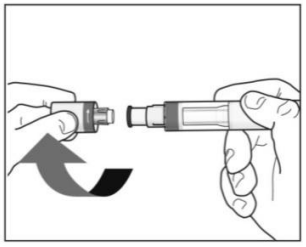


Figure F: remove the cap

4. Holding the pen:

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

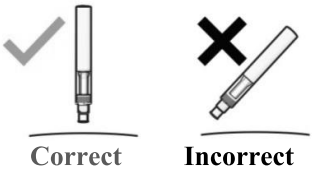


Figure G: hold your pen

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.

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.

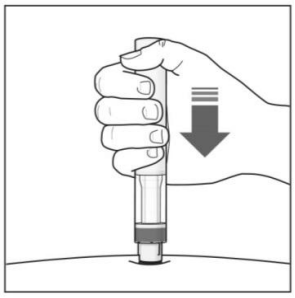


Figure H: start your injection

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.

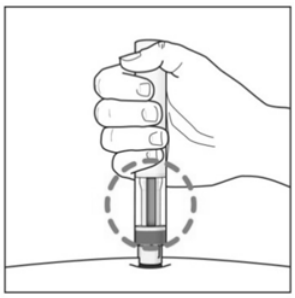


Figure I: complete your injection

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.

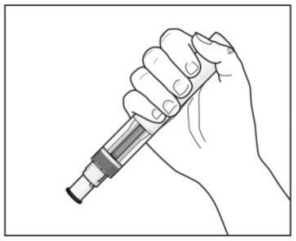
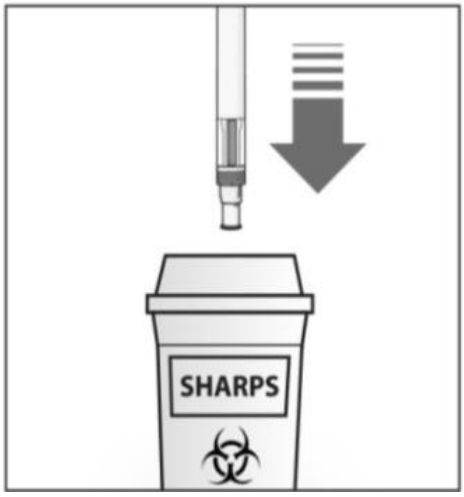


Figure J: check the green indicator

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.