HYRIMOZ®

Adalimumab (rch)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Hyrimoz.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Read this leaflet carefully before you use Hyrimoz and keep it with the medicine.

You may need to read it again.

What HYRIMOZ is used for

The active ingredient in this medicine is adalimumab, a fully human monoclonal antibody. Monoclonal antibodies are proteins made by a type of blood cell to fight a foreign protein in the body. Adalimumab recognises and binds to a specific protein (tumour necrosis factor or TNF-alpha), which is present at increased levels in inflammatory diseases.

Hyrimoz is used for the treatment of:

- Rheumatoid arthritis

Hyrimoz is used to reduce the signs and symptoms of moderately to severely active rheumatoid arthritis, a painful disease of the joints, as well as to slow down and protect against damage to joints. Signs and symptoms of rheumatoid arthritis include joint pain, tenderness, swelling and stiffness.

- Polyarticular Juvenile Idiopathic Arthritis

Hyrimoz is used for reducing the signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis, which is an inflammatory disease, involving multiple joints, in patients 2 years of age and older.

- Enthesitis-related arthritis

Hyrimoz is used to treat enthesitis-related arthritis, an inflammatory disease of the joints in children.

- Psoriatic arthritis

Hyrimoz is used to reduce the signs and symptoms, as well as inhibit the progression of joint damage of moderately to severely active psoriatic arthritis, a disease of the joints and skin, with some similarities to rheumatoid arthritis, as well as psoriasis and other factors.

- Ankylosing spondylitis

Hyrimoz is used to reduce the signs and symptoms in patients with active ankylosing spondylitis, an inflammatory disease of the spine. Signs and symptoms of ankylosing spondylitis include back pain and morning stiffness.

- Non-radiographic axial spondyloarthritis

Hyrimoz is used for the treatment of adult patients with severe axial spondyloarthritis without radiographic evidence of ankylosing spondylitis, an inflammatory disease of the spine. Your doctor will check that you have objective signs of inflammation via a blood test or scan, and will prescribe Hyrimoz only if you have not responded well enough to anti-inflammatory medicines.

- Crohn's Disease

Hyrimoz is used for the treatment of moderate to severe Crohn's disease, an inflammatory disease of the digestive tract, in adults and children aged 6 years and above to reduce the signs and symptoms of the disease and to induce and maintain periods where the symptoms are no longer present. Hyrimoz can be given to patients who have not responded well enough to conventional therapies, or who have lost response to or are intolerant to infliximab (another medicine used to treat Crohn's disease.

- Ulcerative Colitis

Hyrimoz is used for the treatment of moderate to severe ulcerative colitis, an inflammatory bowel disease, in adults and children aged 5 years and above who have not responded well enough to conventional therapy or who are intolerant to or have medical contraindications for such therapies. Patients should show a response within 8 weeks to continue treatment.

- Psoriasis

Hyrimoz is used to treat the signs and symptoms of moderate to severe chronic plaque psoriasis, an inflammatory disease of the skin. Plaque psoriasis can also affect nails, causing them to crumble, thicken and lift away from the nail bed which can be painful.
Hyrimoz is used for moderate to severe forms of the disease in adults and severe forms in children and adolescents from 4 years of age

who have not responded well enough to topical therapy and phototherapy, or who cannot be given those treatments.

- Uveitis

Hyrimoz is used to treat adults with non-infectious intermediate, posterior and pan-uveitis, with inflammation affecting the back of the eye and children from 2 years of age with chronic non-infectious anterior uveitis with inflammation affecting the eye. Inflammation may lead to a decrease of vision and/or the presence of floaters in the eye (black dots or wispy lines that move across the field of vision). Hyrimoz works by reducing this inflammation. Signs and symptoms include inflammation, vision impairment and pain.

- Hidradenitis suppurativa

Hyrimoz is used for the treatment of adult and adolescents from 12 years of age with active moderate to severe hidradenitis suppurativa (acne inversa), 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. Your doctor will schedule follow-up appointments to check on your progress to continue treatment.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is only available with a doctor's prescription.

The long term effects of Hyrimoz on the growth and development of children is not known.

Before you use HYRIMOZ

When you must not use it

Do not use Hyrimoz if you:

- have an allergy to any medicine containing adalimumab or any of the ingredients listed at the end of this leaflet. Symptoms of an allergic reaction may include:

- chest tightness
- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- hives, itching or skin rash

- **have a severe infection including infection of the bloodstream, active tuberculosis and other infections that can be caused by viruses, fungi, parasites or bacteria.**

  Infection occur when the body's natural defences are lowered.

- **are already using anakinra (Kineret) – a medicine for rheumatoid arthritis.**
- **have moderate to severe heart failure.**

Do not use this medicine after the expiry date printed on the label / blister / carton or if the packaging is torn or shows signs of tampering.

Return out of date or damaged medicines to your pharmacist for disposal.

Before you use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- an infection, including a long-term or localised infection (for example, leg ulcer)
- a history of recurrent infections or other conditions that increase the risk of infections

  If you are over 65, you may be more likely to get an infection while taking Hyrimoz. It is important that you and your doctor pay special attention to signs of infection while you are being treated with Hyrimoz.

- a history of tuberculosis, or if you have been in close contact with someone who has had 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.

  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 this medicine. This will include a thorough medical history, a chest x- ray and tuberculin test.

- the hepatitis B virus (HBV) if you are a carrierof, or you have active HBV or you think you might be at risk of contracting HBV.

  Hyrimoz can cause reactivation of HBV in people who carry this virus. In some rare cases, especially if you are taking other medicines that suppress the immune system, reactivation of HBV can be life- threatening.

- a fungal infection, or if you have lived or travelled in countries where some fungal infections are common. These infections may develop or become more severe if you take Hyrimoz.
- If you suffer from uveitis, your doctor may check for signs and symptoms of neurologic disease before starting this medicine.
- multiple sclerosis, a disease of the nervous system or other

demyelinating diseases

- allergic reactions such as chest tightness, wheezing, dizziness, swelling or rash
- blood disorders
- low resistance to disease
- heart conditions including congestive heart failure, heart attack or worsening of existing heart conditions
- cancer or autoimmune disease
- a lung disease called chronic obstructive pulmonary disease (COPD)
- kidney or liver problems

Tell your doctor if you are scheduled for any vaccines.

It is recommended that children, if possible, be brought up to date with all immunisations in agreement with current immunisation guidelines prior to initiating Hyrimoz therapy. Patients receiving Hyrimoz should not receive live vaccines.

Tell your doctor if you are a psoriasis sufferer who has undergone phototherapy.

Tell your doctor if you are pregnant or plan to become pregnant.

A pregnancy study found that there was no higher risk of birth defects when the mother had used adalimumab during pregnancy, compared with mothers with the same disease who did not use adalimumab.

If you use adalimumab during pregnancy, your baby may have a higher risk of getting an infection.

It is important that you tell your baby's doctors and other healthcare professionals about your Hyrimoz use during your pregnancy before the baby receives any vaccine.

Tell your doctor if you are breastfeeding or plan to breastfeed.

If you have not told your doctor or pharmacist about any of the above, tell them before you start using Hyrimoz.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket naturopath or health food shop.

Some medicines and Hyrimoz may interfere with each other. Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

Tell your doctor if you are currently taking or have previously taken any medicine that lowers the body's resistance to disease.

Tell your doctor or pharmacist if you are taking anakinra (Kineret) or abatacept (Orencia), other medicines used to treat some forms of arthritis.

Taking the two medicines together may increase the risk of infection.

Tell your doctor if you are taking azathioprine or 6-mercaptopurine with Hyrimoz.

Hyrimoz can be taken together with medicines such as: methotrexate, and other disease-modifying anti-rheumatic agents (for example, sulfasalazine, hydroxychloroquine, leflunomide and injectable gold preparations), steroids or pain medications including non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen.

Tell your doctor if you are taking any other medicines to treat your condition.

How to use HYRIMOZ

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the label or in this leaflet, ask your doctor or pharmacist for help.

Always use Hyrimoz exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

How much to use

Adults

The usual dose for adults with rheumatoid arthritis is one 40 mg injection every fortnight.

If you are receiving Hyrimoz without methotrexate, your doctor may change your Hyrimoz dose to 40 mg every week or 80 mg every fortnight, depending on your response.

The usual dose for adults with psoriatic arthritis and ankylosing spondylitis is one 40 mg injection fortnightly.The usual dose for adults with Crohn's disease or ulcerative colitis is an initial dose of 160 mg (given as four 40 mg injections on one day or two 40 mg injections a day over two days), followed by 80 mg two weeks later (given as two 40 mg injections on one day) then 40 mg starting two weeks later and continuing every fortnight.

Your doctor may change this ongoing (maintenance) dose to 40 mg every week or 80 mg every fortnight depending on your response.

The usual dose for adults with psoriasis or uveitis is an initial dose of 80 mg, followed by 40 mg given fortnightly starting one week after the initial dose.

For adults with psoriasis, depending on your response, your doctor may increase the dose frequency to 40 mg every week or 80 mg every fortnight.

The usual dose for adults with hidradenitis suppurativa is an initial dose of 160 mg (given 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 a further two weeks, continue with a dose of 40 mg every week or 80 mg every fortnight.

Your doctor may prescribe other medicines for your condition arthritis to take with this medicine.

Children

For children with polyarticular juvenile idiopathic arthritis, 2 years and older, or enthesitis-related arthritis 6 years and older

- with a body weight of 30 kg or above, the usual dose is 40 mg given fortnightly.
- with a body weight between 10 kg and less than 30 kg, the usual dose is 20 mg given every fortnight.

The usual dose for children with Crohn's disease depends on body weight.

For a body weight of 40 kg or above:

The initial dose is 160 mg (given as four 40 mg injections in one day OR as two 40 mg injections per day for two consecutive days), followed by an 80 mg dose two weeks later (given as two 40 mg injections in one day). After a further two weeks, continue with a dose of 40 mg every fortnight.

Your doctor may change this ongoing (maintenance) dose to 40 mg every week or 80 mg every fortnight, depending on your response.

For a body weight of less than 40 kg:

The initial dose is 80 mg (given as two 40 mg injections in one day), followed by a 40 mg dose two weeks later. After a further two weeks, continue with a dose of 20 mg every fortnight.

Your doctor may change this ongoing (maintenance) dose to 20 mg every week, depending on your response.

Treatment of Crohn's disease in children should be supported by good nutrition to allow appropriate growth.

The usual dose for children with psoriasis depends on the body weight:

- with a body weight of 30 kg or above, the usual dose is 40 mg given once weekly for the first two weeks, then fortnightly.
- with a body weight of less than 30 kg, the usual dose is 20 mg given once weekly for the first two weeks, then fortnightly.

If Hyrimoz has no effect on the child's condition after 16 weeks, your doctor may tell you to stop using Hyrimoz.

For children with non-infectious anterior uveitis aged 2 years or older, the dose depends on body weight.

- With a body weight of 30 kg or more, the usual dose is 40 mg fortnightly with methotrexate. Your child's doctor may also prescribe an initial dose of 80 mg which may be administered one week prior to the start of the usual dose.
- With a body weight of less than 30 kg, the usual dose is 20 mg fortnightly with methotrexate. Your child's doctor may also prescribe an initial dose of 40 mg which may be administered one week prior to the start of the usual dose.

Your doctor may prescribe other medicines for your child's condition to take with this medicine.

The usual dose for adolescents (from 12 years, weighing at least 30 kg) with hidradenitis suppurativa is an initial dose of 80 mg (two 40 mg injections in one day), followed by 40 mg fortnightly starting one week later. If you do not respond well enough, your doctor may increase the dose to 40 mg every week or 80 mg every fortnight.

It is recommended you use an antiseptic body wash daily on the affected areas.The usual dose for children with ulcerative colitis depends on body weight:

- with a body weight of 40 kg or above, the initial dose is 160 mg, followed by 80 mg two weeks later, then continuing with 80 mg every fortnight OR 40 mg weekly.
- with a body weight of less than 40 kg, the initial dose is 80 mg, followed by 40 mg two weeks later, then continuing with 40 mg every fortnight OR 20 mg weekly.

How to use it

Hyrimoz is injected under the skin. The injection can be self-administered or given by another person, for example a family member or friend after proper training in injection technique, or your doctor or his / her assistant.

Comprehensive instructions are given in the "**Instructions for use for Hyrimoz pre-filled syringe / Hyrimoz SensoReady® pen**".

How long to use it

Keep using Hyrimoz for as long as your doctor tells you.

Hyrimoz will not cure your condition but should help control your symptoms.

Ask your doctor if you are not sure how long to take this medicine for.

If you forget to use it

If you forget to give yourself an injection, you should inject the next dose of Hyrimoz as soon as you remember. Then inject your next dose as you would have on your originally scheduled day, had you not forgotten a dose. Do not try to make up for missed doses by taking more than one dose at a time.
This may increase the chance of getting an unwanted side effect.

If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.

If you are not sure what to do, ask your doctor or pharmacist.

If you take too much (overdose)

If you accidentally inject Hyrimoz more frequently than told to by your doctor, immediately telephone your doctor or the Poisons Information Centre (Telephone 0800 764 766), or go to Accident and Emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention. Always take the outer carton of the medicine with you.

While you are using HYRIMOZ

Things you must do

Check with your doctor before you receive any vaccines.

It is recommended that children, if possible, be brought up to date with all immunisations in agreement with current immunisation guidelines prior to initiating Hyrimoz therapy.

Some vaccines, such as oral polio vaccine, should not be given while receiving Hyrimoz.

If you become pregnant while using Hyrimoz, tell your doctor immediately.

If you are about to be started on any new medicine, tell your doctor you are using Hyrimoz.

Tell all doctors, dentists, and pharmacists who are treating you that you are using Hyrimoz.

If you are going to have surgery, tell the surgeon or anaesthetist that you are using Hyrimoz.

Your doctor may recommend temporary discontinuation of Hyrimoz.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

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

Do not use Hyrimoz to treat any other complaints unless your doctor tells you to.

Do not stop taking Hyrimoz, without checking with your doctor.

Do not take Hyrimoz and anakinra (Kineret) together.

Do not take Hyrimoz and abatacept (Orencia) together.

Anakinra and abatacept are other medicines used to treat certain forms of arthritis. Taking the two medicines together with Hyrimoz may increase the risk of developing a serious infection

Things to be careful of

It is important to tell your doctor if you get symptoms such as fever, wounds, feeling tired or dental problems.

You might get infections more easily while you are receiving Hyrimoz-treatment. These infections may be serious and include tuberculosis, infections caused by viruses, fungi or bacteria, or other opportunistic infections and sepsis that may, in rare cases, be life- threatening. Your doctor may recommend temporary discontinuation of Hyrimoz.

Be careful driving or operating machinery until you know how Hyrimoz affects you.

The effects on your ability to drive and use machines whilst taking this medicine are not known.

Side effects

Tell your doctor as soon as possible if you have any problems while using Hyrimoz, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist any questions you may have.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital, if you experience any of the following:

- signs of an allergic reaction such as:
    - chest tightness
    - shortness of breath, wheezing or difficulty breathing
    - swelling of the face, lips, tongue or other parts of the body
    - hives, itching or skin rash
- signs and symptoms suggestive of heart failure, such as 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

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are uncommon.

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

- signs of tuberculosis such as persistent cough, weight loss, listlessness, fever
- signs of infection such as fever, lack of energy, malaise, skin sores, wounds, dental problems, burning on urination. You

might get infections more easily while you are receiving Hyrimoz treatment.

- signs of nervous system disorders such as numbness or tingling throughout your body, arm or leg weakness, double vision
- signs of soft tissue infection, such as a bump or open sore that doesn't heal

The above list includes serious side effects. You may need urgent medical attention. Serious side effects are rare.

Tell your doctor if you notice any of the following and they worry you:

- Injection site reactions (including pain, swelling, redness or itching)
- Upper respiratory tract infections (including cold, runny nose, sinus infection, sore throat, cough, congestion on the chest, asthma or worsening of asthma symptoms)
- Lower respiratory tract infections (such as bronchitis, pneumonia)
- Pain in the ear which could suggest ear infection
- Pain or inflammation of the eyes or eye lid or changes to your vision
- Burning or pain when passing urine, or blood in urine
- Skin bumps or sores that don't heal
- Headache, dizziness, vertigo, sensation disorders
- Muscle weakness or numbness, difficulty balancing
- Increased cough, sore throat
- Fever, flushing, increased sweating
- Abdominal symptoms such as nausea, diarrhoea, abdominal pain,
- Reflux or heartburn
- Chest pain
- Rash, itching, redness or scaly patches
- Problems with your finger or toe nails
- Hair loss
- Fatigue, tiredness, lack of energy
- Mouth inflammation and ulcers, pain or excessive bleeding from the gums
- Muscle or bone pain
- Bleeding or bruising more easily than usual
- Feeling overwhelmed or sad, or lack of motivation (depression)
- Feeling anxious, especially fearful or worried (anxiety)
- Increased heart rate
- Viral infections (including the flu, cold sore blisters, chicken pox and shingles)
- Bacterial infections (including urinary tract infection)
- Fungal infections

The above list includes the more common side effects of Hyrimoz. They are usually mild and short-lived.

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 chance of getting a kind of cancer that affects the lymph system, called lymphoma, or that affects the blood, called leukaemia. If you take Hyrimoz your risk may increase.

On rare occasions, a specific and severe type of lymphoma has been observed in patients taking Hyrimoz.

Some of those patients were also treated with azathioprine or 6-mercaptopurine. In addition very rare cases of skin cancer have been observed in patients taking Hyrimoz. If new skin lesions appear during or after therapy or if existing lesions change appearance, tell your doctor.

There have been cases of cancers other than lymphoma in patients with a specific type of lung disease called Chronic Obstructive Pulmonary Disease (COPD) treated with another TNF blocker.

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

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may occur in some people.

After using HYRIMOZ

Storage

Keep your pre-filled syringe / pre-filled pen in the pack until it is time to use it.

Keep Hyrimoz in a refrigerator (2 °C–8 °C). Do not freeze.

Keep Hyrimoz in the refrigerator in a way children cannot get to it.

If needed (for example when you are travelling), Hyrimoz may be stored up to a maximum of 25 °C for a period of up to 21 days – be sure to protect it from light. When you remove your pre-filled syringe / pre-filled pen from the refrigerator and it has warmed to room temperature, your pre-filled syringe / pre-filled pen **must be used within 21 days or discarded**, even if it is later returned to the refrigerator.

Write down the date you first removed the syringe / pen from the refrigerator on the label, so you can check how long it has been.

For additional information about Hyrimoz, contact Sandoz Medical Information on 0800 354 335.

Disposal

After injecting Hyrimoz, throw away the used pre-filled syringe / pre-filled pen immediately in a

special "sharps" container as instructed by your doctor, nurse or pharmacist.

If your doctor tells you to stop using Hyrimoz or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Hyrimoz is a colourless to slightly yellowish as well as clear to slightly opalescent solution of:

- 40 mg adalimumab in 0.8 mL water in a syringe
- 20 mg adalimumab in 0.4 mL water in a syringe

Hyrimoz 40 mg is available in a pre-filled syringe with needle guard / pre-filled pen for patient use.

Hyrimoz 20 mg is available in a pre-filled syringe with needle guard.

Packs containing 1, 2 or 6 pre-filled syringe(s) / pre-filled pen(s) are available. Not all presentations may be marketed.

Ingredients

Hyrimoz contains 20 mg or 40 mg of adalimumab as the active ingredient.

It also contains other inactive ingredients:

- adipic acid
- Citric acid monohydrate
- Sodium chloride
- mannitol
- polysorbate 80
- hydrochloric acid
- sodium hydroxide
- water for injections

Sponsor

Hyrimoz is distributed in New Zealand by:

Sandoz New Zealand Limited

Auckland

Telephone: 0800 729 369

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