

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Hyrimoz?

Hyrimoz contains the active ingredient adalimumab. Hyrimoz is used to treat various inflammatory conditions.

For more information, see Section [1. Why am I using Hyrimoz?](#) in the full CMI.

2. What should I know before I use Hyrimoz?

Do not use if you have ever had an allergic reaction to Hyrimoz or any of the ingredients listed at the end of the CMI.

Talk to your doctor before you take this medicine if he/she is not aware that you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Hyrimoz?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Hyrimoz and affect how it works, or Hyrimoz may interfere with other medicines and affect how they work.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Hyrimoz?

Hyrimoz is injected under the skin (subcutaneous).

More instructions can be found in Section [4. How do I use Hyrimoz?](#) in the full CMI.

5. What should I know while using Hyrimoz?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Hyrimoz.• Keep all your appointments, including for blood tests.• Tell your doctor if you develop an infection or you notice new or changed spots on your skin.• Tell your doctor if you are scheduled for any vaccines.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine or change the dose unless your doctor tells you to.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines until you know how Hyrimoz affects you. The effects on your ability to drive or use machines whilst taking Hyrimoz is not known.
Drinking alcohol	<ul style="list-style-type: none">• There is no information on the effects of taking Hyrimoz with alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Store Hyrimoz in the refrigerator (2 °C to 8 °C). Do not freeze.• Keep pens or syringes in the pack to protect your medicines from light.

For more information, see Section [5. What should I know while using Hyrimoz?](#) in the full CMI.

6. Are there any side effects?

Side effects that require urgent medical attention include: Signs of an allergic reaction, such as chest tightness, difficulty breathing, swelling of face lips and tongue, rash; signs of heart failure, such as shortness of breath on exertion or lying down, swelling of the feet; signs suggesting a blood disorder, such as persistent fever, bruising, bleeding, paleness.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

HYRIMOZ®

Active ingredient(s): *adalimumab (rch)* (a-da-li-mue-mab)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Hyrimoz. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Hyrimoz.**

Where to find information in this leaflet:

- [1. Why am I using Hyrimoz?](#)
- [2. What should I know before I use Hyrimoz?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Hyrimoz?](#)
- [5. What should I know while using Hyrimoz?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Hyrimoz?

Hyrimoz contains the active ingredient **adalimumab**.

Hyrimoz is used to treat rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, enthesitis-related arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease in adults and children aged 6 years and over, ulcerative colitis, psoriasis in adults and children 4 years and over, hidradenitis suppurativa in adults and adolescents from 12 years and over, and uveitis.

2. What should I know before I use Hyrimoz?

Warnings

Do not use Hyrimoz if:

- you are allergic to adalimumab, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you have a severe infection such as sepsis (a serious infection of the blood) or tuberculosis (a serious infection of the lungs caused by bacteria), or other severe infection caused by a virus, fungus, parasite or bacteria
- you have heart failure considered by your doctor to be moderate or severe.

Check with your doctor if you:

- have or have had an infection that does not go away or keeps coming back, this can include leg ulcers
- you have ever had tuberculosis, or you have been in close contact with someone who has tuberculosis. Tuberculosis can develop during therapy even if you

have received treatment for the prevention of tuberculosis.

- you currently have active hepatitis B, have ever had hepatitis B, are a carrier of the hepatitis B virus or you think you may be at risk of contracting hepatitis B
- you have or have had an infection caused by a fungus, or you have lived or travelled in countries where fungal infections are common
- you have or have had uveitis, where the middle layer of the eyeball is inflamed
- you have or have had allergic reactions such as chest tightness, wheezing, dizziness, swelling or rash
- you have a disease that affects the insulating layer of the nerves, e.g. multiple sclerosis (MS)
- you have or have had a blood disorder
- you have or have had low resistance to disease
- you have or have had a heart condition
- you have or have had cancer or autoimmune disease
- you have a lung disease called chronic obstructive pulmonary disease (COPD)
- you have or have had kidney or liver problems
- you have any vaccinations scheduled
- you have or have had psoriasis (a skin disease that produces patches of thickened, scaly skin that is not contagious)
- you have had phototherapy, also known as light therapy, for psoriasis
- you have any surgery planned
- you take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Hyrimoz should only be used in pregnancy if clearly needed.

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

You should consider the use of effective contraception to prevent pregnancy and continue its use for at least 5 months after the last Hyrimoz injection.

Tell your baby's doctor if you have taken Hyrimoz while you are pregnant, especially before your baby receives any vaccinations.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Use in children

- Wherever possible, it is recommended that children are up to date with all vaccinations, according to current immunisation guidelines, before they are started on Hyrimoz treatment.

- Treatment of Crohn's disease in children should be supported by good nutrition to allow appropriate growth.
- The long-term effects of Hyrimoz on the growth and development of children is not known.

Use in the elderly

If you are over 65, you may be more likely to get an infection while taking Hyrimoz.

3. What if I am taking other medicines?

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

Some medicines may interfere with Hyrimoz and affect how it works, while Hyrimoz may affect how other medicines work.

Do not take Hyrimoz if you are taking the following medicine:

- anakinra, a medicine used to treat rheumatoid arthritis, juvenile idiopathic arthritis and conditions associated with a defect in a protein called cryoprin.

Medicines that may increase the risk of infection when taken with Hyrimoz include:

- anakira, a medicine used to treat rheumatoid arthritis, juvenile idiopathic arthritis and conditions associated with a defect in a protein called cryoprin
- abatacept, a medicine used to treat rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis
- azathioprine, a medicine used for suppressing the immune system to treat various conditions
- 6-mercaptopurine, a medicine used to treat certain types of leukaemia, a blood disorder.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Hyrimoz.

4. How do I use Hyrimoz?

How much to take

- **Rheumatoid arthritis in adults**
Inject one 40 mg dose every fortnight.
If you are **not** taking methotrexate, your doctor may change this dose to 40 mg every week, or 80 mg every fortnight, depending on your response.
- **Psoriatic arthritis and ankylosing spondylitis in adults**
Inject one 40 mg dose every fortnight.
- **Crohn's disease and ulcerative colitis in adults**
Inject 160 mg on day 1, followed by 80 mg on day 15 and 40 mg on day 29. Then, continue to inject 40 mg every fortnight (maintenance dose).

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

(See **Special dosing instructions** at the end of this section.)

- **Psoriasis in adults**

Inject 80 mg on day 1, followed by 40 mg on day 8 and 40 mg on day 22. Then, continue to inject 40 mg every fortnight (maintenance dose). Your doctor may change this maintenance dose to 40 mg every week, or 80 mg every fortnight, depending on your response.

(See **Special dosing instructions** at the end of this section.)

- **Uveitis in adults**

Inject 80 mg on day 1, followed by 40 mg on day 8 and 40 mg on day 22. Then continue to inject 40 mg every fortnight (maintenance dose).

(See **Special dosing instructions** at the end of this section.)

- **Hidradenitis suppurativa in adults**

Inject 160 mg on day 1, followed by 80 mg on day 15. Then continue to inject 40 mg every week or 80 mg every fortnight from day 29 (maintenance dose).

(See Special dosing instructions at the end (See **Special dosing instructions** at the end of this section.)

- **Polyarticular juvenile idiopathic arthritis and enthesitis-related arthritis**

If the patient's body weight is at least 30 kg, inject one 40 mg dose every fortnight.

There is no available dosage form of Hyrimoz that allows dosage of less than 40 mg.

- **Crohn's disease in children**

If the patient's body weight is at least 40 kg, inject 160 mg on day 1, followed by 80 mg on day 15 and 40 mg on day 29. Then, continue to inject 40 mg every fortnight (maintenance dose).

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

(See **Special dosing instructions** at the end of this section.)

- **Psoriasis in children**

If the patient's body weight is at least 40 kg, inject 40 mg on day 1, followed by 40 mg on day 8 and 40 mg on day 22. Then continue to inject 40 mg every fortnight (maintenance dose).

- **Hidradenitis suppurativa (HS) in adolescents**

If the patient's body weight is at least 30 kg, inject 80 mg on day 1, followed by 40 mg on day 8, and 40 mg on day 22. Then continue to inject 40 mg every fortnight (maintenance dose).

Your doctor may change this maintenance dose to 40 mg every week, or 80 mg every fortnight depending on your response.
(See **Special dosing instructions** at the end of this section.)

Use an antiseptic body wash daily on the affected areas.

Special dosing instructions

- When a dose of 160 mg is required, this can be given as two 80 mg OR four 40 mg injections in one day, or one 80 mg or two 40 mg injections per day over two consecutive days.
- When a dose of 80 mg is required, this can be given as one 80 mg injection or two 40 mg injections in one day.

In some instances, Hyrimoz needs to be taken with other medicines. Your doctor will let you know which medicines, how to take them and how long to take them.

Follow all instructions given to you and use Hyrimoz until your doctor tells you to stop.

How to use Hyrimoz

- Hyrimoz is injected under the skin (sub-cutaneous injection).
- It can be injected by the patient, or by someone else, such as a family member, friend, carer after proper training in injection technique, or your doctor or his/her assistant.
- An injection should not be attempted until proper training has been received on the correct injection technique.
- Do not mix the injection with any other medicine.
- Comprehensive instructions are given in the "Instructions for use for Hyrimoz pre-filled syringe / Hyrimoz SensoReady® pen".

If you forget to inject Hyrimoz

It is important that you use your medicine as prescribed by your doctor.

If you miss your dose at the usual time, inject Hyrimoz as soon as you remember, and continue injecting the next dose at the usual time on your scheduled day.

Do not take a double dose to make up for the dose you missed.

If you inject too much Hyrimoz

If you think that you have injected too much Hyrimoz you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Hyrimoz?

Things you should do

- Keep all your doctor's appointments so your progress can be tracked.
- Keep your appointments for blood tests. Some side effects are seen in blood results before you have any symptoms.
- Remind any doctor, dentist or pharmacist you visit that you are using Hyrimoz, especially if you are scheduled for surgery or to receive any live vaccines (e.g. Bacille Calmette-Guerin or oral polio vaccine).

Call your doctor straight away if you:

- get symptoms of an infection, such as fever, skin sores, feeling tired, any problems with your teeth or gums or pain when passing urine or blood in your urine.
- become pregnant while using Hyrimoz.
- notice new skin lesions (skin spots or sores), or if existing lesions change appearance.

Things you should not do

- Do not stop using this medicine or change the dose without checking with your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Hyrimoz affects you.

Drinking alcohol

There is no information on the use of alcohol with Hyrimoz.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

- Keep your pre-filled syringe / pre-filled pen in the pack until it is time to use it.
- Protect from light.
- Keep Hyrimoz in a refrigerator (2 °C–8 °C). Do not freeze. Do not shake.

Keep it where young children cannot reach it.

When to discard your medicine

- Protect from light.
- Keep Hyrimoz in a refrigerator (2 °C–8 °C). Do not freeze. Do not shake.
- When necessary, a single Hyrimoz pen or syringe may be stored at room temperature (25 °C) for a period of up to 21 days, protected from light.
- Once removed from the refrigerator, your pre-filled syringe / pre-filled pen must be used within 21 days or

discarded, even if it is later returned to the refrigerator.

- After injecting Hyrimoz, immediately throw away the used pre-filled syringe / pre-filled pen in a special “sharps” container as instructed by your doctor, nurse or pharmacist.

For additional information about Hyrimoz, contact Sandoz Medical Information on 1800 726 369.

Getting rid of any unwanted medicine

If your doctor advises that you no longer need to use this medicine or it is out of date, follow local guidelines for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Injection site <ul style="list-style-type: none"> • pain • swelling • redness • itching Lungs and upper airways <ul style="list-style-type: none"> • cold • flu • runny nose • cough • sore throat • sinus infection • asthma or worsening asthma • bronchitis or pneumonia (congestions on the chest) Ears, eyes and mouth <ul style="list-style-type: none"> • pain in the ear • pain, redness or swelling of the eye or eye lid • changes to vision • mouth ulcers • pain in the gums • excessive bleeding from the gums Brain and nerves <ul style="list-style-type: none"> • headache or migraine • dizziness • muscle weakness • muscle, bone or joint pain • numbness • difficulty balancing Gut and digestion <ul style="list-style-type: none"> • nausea • vomiting 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

<ul style="list-style-type: none"> • tummy pain • reflux or heartburn Skin and nails <ul style="list-style-type: none"> • rash • itching • redness • scaly skin patches • problems with your fingernails or toenails • hair loss • core sore blisters • chicken pox Blood <ul style="list-style-type: none"> • bleeding • bruising more easily than usual Body as a whole <ul style="list-style-type: none"> • tiredness • chest pain • lack of energy • increased heart rate • feeling overwhelmed or sad, lacking motivation (depression) • feeling especially fearful or worried (anxiety) 	
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Serious side effects

Serious side effects	What to do
Signs of tuberculosis, such as: <ul style="list-style-type: none"> • persistent cough • weight loss • listlessness • fever. Signs of an infection, such as: <ul style="list-style-type: none"> • fever • lack of energy • skin bump or sore that doesn't heal • problems with your teeth or gums • pain when passing urine or blood in the urine. Signs of problems with your nervous system, such as: <ul style="list-style-type: none"> • numbness • tingling throughout your body • arm or leg weakness • double or blurred vision. Signs suggesting a blood clot, such as : <ul style="list-style-type: none"> • swelling, tenderness, redness and a warm feeling of an area of the arm or leg 	<p>Speak to your doctor as soon as possible if you have any of these side effects.</p>

Very serious side effects

Serious side effects	What to do
Signs of an allergic reaction, such as: <ul style="list-style-type: none"> • chest tightness, 	<p>Call your doctor straight away, or go straight</p>

<ul style="list-style-type: none"> • shortness of breath, wheezing or difficulty breathing, • swelling of the face, lips, tongue or other parts of the body, • hives, itching or skin rash. <p>Signs of heart failure, such as:</p> <ul style="list-style-type: none"> • shortness of breath on exertion or lying down, • swelling of the feet. <p>Signs suggesting a blood disorder, such as:</p> <ul style="list-style-type: none"> • persistent fever, • bruising, • bleeding very easily • paleness. 	<p>to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>
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Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

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

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Hyrimoz contains

Active ingredient (main ingredient)	adalimumab
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • adipic acid • citric acid monohydrate • sodium chloride • mannitol • polysorbate 80 • hydrochloric acid • sodium hydroxide • water for injections

Do not take this medicine if you are allergic to any of these ingredients.

What Hyrimoz contains

Hyrimoz in 40 mg in 0.8 mL

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

- 40 mg adalimumab in 0.8 mL solution in a pre-filled syringe (AUST R 291937)
- 40 mg adalimumab in 0.8 mL solution in a pre-filled pen (AUST R 291938)

What Hyrimoz looks like

Pre-filled syringe with needle guard / pre-filled pen for patient use in packs containing 1, 2 or 6 pre-filled syringe(s) / pre-filled pen(s)*.

**Not all pack sizes or presentations may be marketed*

Who distributes Hyrimoz

Sandoz Pty Ltd

ABN 60 075 449 553

54 Waterloo Road

Macquarie Park, NSW 2113

Tel: 1800 726 369

This leaflet was revised in July 2022.