

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 Erelzi?

Erelzi contains the active ingredient etanercept. Erelzi is used to treat specific types of joint inflammation and skin conditions, namely rheumatoid arthritis, juvenile idiopathic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis (nr-AxSpA), psoriatic arthritis and plaque psoriasis.

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

2. What should I know before I use Erelzi?

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

Talk to your doctor if 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 Erelzi?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Erelzi and affect how it works.

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 Erelzi?

- Erelzi is given in adults either once a week as a 50 mg dose, or as two separate 25 mg doses 3-4 days apart. In children, the dose and frequency depend on weight and the disease.
- Erelzi is injected under the skin and is for single use in one patient only. Refer to Instructions for Use provided in the pack.

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

5. What should I know while using Erelzi?

Things you should do	<ul style="list-style-type: none">• Remind any doctor or dentist you visit that you are using Erelzi.• Ensure children are up to date with vaccinations prior to starting Erelzi.• Tell your doctor if you are at risk of blood poisoning or infections, such as leg ulcers.• Contraception is recommended to avoid becoming pregnant during Erelzi therapy and for 3 weeks after discontinuation of Erelzi therapy. Inform your doctor immediately if you are planning pregnancy or are pregnant.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly, unless advised by your doctor.
Looking after your medicine	<ul style="list-style-type: none">• Keep Erelzi in the fridge between 2°C and 8°C. Do not freeze.• If it is not possible to store Erelzi in the refrigerator, it may be stored out of the refrigerator (up to 25°C) for up to 4 weeks (e.g. when travelling); after which it should not be refrigerated again.• Store Erelzi in the cartons to protect from light.

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

6. Are there any side effects?

Common side effects include a mild reaction in the area of injection, infections and inflammation, allergic reactions, rash, itching, fever, headache and raised liver enzymes.

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.

Consumer Medicine Information (CMI)

This leaflet provides important information about using Erelzi. **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 Erelzi.**

Where to find information in this leaflet:

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

1. Why am I using Erelzi?

Erelzi contains the active ingredient etanercept.

Etanercept is a biotechnology-derived protein that works by binding to and inactivating Tumour Necrosis Factor (TNF), a naturally occurring chemical in your bloodstream that contributes to pain and swelling in the joints.

Erelzi is used in the treatment of specific inflammatory joint or skin conditions by reducing the pain and swelling of rheumatoid arthritis and psoriasis, helping to treat the skin lesions of psoriasis and psoriatic arthritis, and improving the condition of patients with ankylosing spondylitis, non-radiographic axial spondyloarthritis (nr-AxSpA) and juvenile idiopathic arthritis.

Your doctor may have prescribed Erelzi for another reason. Ask your doctor if you have any questions about why Erelzi has been prescribed for you.

2. What should I know before I use Erelzi?

Warnings

Do not use Erelzi if:

- you are allergic to etanercept 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, or are at risk of developing, sepsis (blood poisoning), or long-term or localised infection (for example, leg ulcers).
Sepsis is a serious infection causing fever, headache, joint aches and pains, sore or weak muscles, and increased heart rate. Erelzi can affect your body's ability to fight a serious infection.
If you are not sure whether you have a serious infection, check with your doctor.

- you are currently taking anakinra or other similar medicines known as Interleukin-1 antagonists.
- the packaging is torn or shows signs of tampering
- the expiry date printed on the pack has passed.
If you use Erelzi after the expiry date has passed, it may have no effect at all, or worse, have an entirely unexpected effect.

Check with your doctor if you:

- have any allergies to:
 - any other medicines,
 - any other substances, such as foods, preservatives or dyes.
- have any other medical conditions, especially:
 - serious infection including sepsis, tuberculosis or a history of recurring infections,
 - low resistance to disease,
 - diabetes,
 - liver problems or hepatitis B or hepatitis C, viruses that affect the liver,
 - heart failure,
 - blood disorders,
 - cancer,
 - are about to have major surgery,
 - nerve disorders including multiple sclerosis or optic neuritis (inflammation of the nerves of the eyes),
 - seizures,
 - chickenpox or have been recently exposed to chickenpox.
- take any medicines for any other condition,
- you are pregnant or intend to become pregnant,
- you are breast-feeding or plan to breast-feed.

If you are not sure whether you should start taking this medicine, talk to your doctor.

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.

The effects of etanercept in pregnant women are not well understood, therefore Erelzi should only be used during pregnancy if clearly needed.

Contraception is recommended to avoid becoming pregnant during Erelzi therapy and for 3 weeks after discontinuation of Erelzi therapy. Inform your doctor immediately if you are planning pregnancy or are pregnant.

If you become pregnant while using Erelzi, contact your doctor. Your doctor will help you to decide whether the

benefits of treatment outweigh the potential risk to your baby.

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

Small amounts of etanercept can pass into breast milk. If you are breastfeeding, you should discuss the use of Erelzi and the options available with your doctor.

It is important that you discuss with your doctor the use of Erelzi during pregnancy or breastfeeding before the baby receives any vaccine.

Use in Children

- Erelzi is not currently recommended for use in children under 2 years of age as it has not been tested in children under 2 years.
- Make sure that children are up to date with all vaccinations (including chickenpox) before they start treatment with Erelzi.
Live vaccines, such as oral polio vaccine, should not be given while receiving Erelzi.
- Erelzi is not available in a dose suitable for use in children and adolescents weighing less than 62.5 kg. Children and adolescents weighing less than 62.5 kg should be accurately dosed on a mg/kg basis with other etanercept products.

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

Erelzi is not addictive.

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 Erelzi and affect how it works.

Medicines that increase risk of side effects when used with Erelzi:

- abatacept and Interleukin-1 antagonists such as anakinra. These medicines should not be used with Erelzi.
- cyclophosphamide, a medicine used to treat cancer or prevent transplant rejection. Use with Erelzi is not recommended.
- sulfasalazine.

Medicines that Erelzi may interfere with:

- some vaccines
- warfarin, a medicine used to thin the blood and prevent blood clots
- digoxin, a medicine used to improve the strength and efficiency of the heart, or to control the rate and rhythm of the heartbeat
- medicines used to treat diabetes

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

4. How do I use Erelzi?

Your doctor will tell you how to inject Erelzi. A different site should be used for each new injection. Each new injection should be given at least 3 cm from an old site.

How much to take

Adults

- The recommended dose for adults is 50 mg per week, injected under the skin. This can be given as either a single 50 mg injection once weekly, or two separate 25 mg injections, 3-4 days apart. Your doctor may determine a different frequency at which to inject Erelzi.
- If you are being treated for psoriasis, your doctor may prescribe a higher dose of Erelzi when you first begin your treatment.
- If you are being treated for nr-AxSpA and Erelzi has no effect on your condition within 12 weeks, your doctor may tell you to stop using this medicine
- Follow the instructions provided and use Erelzi until your doctor tells you to stop.

Children

- The appropriate dose and frequency of dosing for children and teenagers will depend on body weight and the disease. Your child's doctor will provide detailed directions for choosing the appropriate dose for your child.
- Erelzi is available for treatment of children and adolescents weighing 62.5 kg or more. Children and adolescents weighing less than 62.5 kg should be accurately dosed on a mg/kg basis with other etanercept products.

When to take Erelzi

- Erelzi should be used at the same time each week or at the same time every 3-4 days as directed by your doctor.

How to take Erelzi

- After allowing the Erelzi solution to reach room temperature (approximately 15 to 30 minutes), immediate use is recommended. Each pre-filled syringe or auto-injector of Erelzi is for single use only, in one patient only. Discard after use.
- **Follow all directions given to you by your doctor and pharmacist carefully.**
- They may differ from the information contained in this leaflet.
- **If you are injecting Erelzi yourself, you must follow the detailed instructions provided in the leaflet inside the pack.**
- Erelzi is injected under the skin. When using the syringes provided with the Erelzi pre-filled syringe presentations, it is important that you do not pull back on the plunger. Erelzi can be injected by your doctor, nurse, carer or by yourself.
- **When you have finished injecting Erelzi, discard the pre-filled syringe or the auto-injector into a sharps container.**

- **If you do not understand the instructions for injecting Erelzi found in the carton, ask your doctor or pharmacist for help.**
- **To help you remember, use a diary to write in the days of the week you or your child should have an Erelzi injection.**

If you forget to use Erelzi

Erelzi should be used regularly at the same time each week, or the same time every 3-4 days as agreed with your doctor. If you miss your dose at the usual time, you should inject the next dose as soon as you remember if it is within 48 hours since the scheduled dose time.

If it is almost time for your next dose i.e. within 48 hours of your next dose, skip the dose you missed and take your next dose when you are meant to.

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

If you use too much Erelzi

If you think that you have used too much Erelzi, you may need urgent medical attention.

You should immediately:

- phone the Australian Poisons Information Centre (**by calling 13 11 26**), or the New Zealand National Poisons Information Centre (**by calling 0800 POISONS or 0800 764766**), 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.

Always take the labelled medicine carton with you, even if it is empty.

You may need urgent medical attention. There is very limited data on overdose with Erelzi. Ask your doctor if you have any concerns.

5. What should I know while using Erelzi?

Things you should do

Tell any other doctors, dentists and pharmacists who are treating you that you are using Erelzi.

Tell your doctor if Erelzi is not making your condition better.

Keep a record of the Lot number of each Erelzi pack that you use.

Call your doctor straight away if you:

- have or develop any serious infection while using Erelzi. Do not inject any more Erelzi and contact your doctor immediately.
- have any symptoms such as persistent fever, sore throat, bruising, bleeding or paleness. These symptoms may point to the existence of a potentially life-threatening blood disorder, which may require you to stop taking Erelzi.

Remind any doctor or dentist you visit that you are using Erelzi.

Things you should not do

- Do not stop using this medicine suddenly or lower the dosage without checking with your doctor.
- Do not stop using Erelzi because you are feeling better, unless your doctor advises you to. Your condition may flare up if you reduce the dose or stop using Erelzi.
- Do not give Erelzi to anyone else even if they have the same condition as you.
- Do not use Erelzi to treat any other complaints unless your doctor tells you to.
- Do not stop using Erelzi, or lower the dosage, without checking with your doctor.

Driving or using machines

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

It is not known whether Erelzi causes dizziness or drowsiness.

Drinking alcohol

No information is available.

Looking after your medicine

- **Keep Erelzi in a refrigerator where the temperature stays between 2°C and 8°C. Do not freeze.**

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

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Store Erelzi prefilled syringes and auto-injectors in their cartons to protect them from light.

Heat and dampness can destroy some medicines.

If it is not possible to store Erelzi in the refrigerator, it may be stored out of the refrigerator (below 25°C) for up to 4 weeks (e.g. when travelling).

If you have stored Erelzi at room temperature for any period of time (even if returned to the refrigerator) you must use it within 4 weeks from the time you first took it out of the refrigerator, or else you must discard it.

Do not use Erelzi if it has been exposed to high temperatures or has been out of the refrigerator for more than 4 weeks.

For additional advice on storing Erelzi, contact Sandoz Medical Information on 1800 726 369 (Australia) or 0800 726 369 (New Zealand).

Do not use this medicine after the expiry date.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

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.

Common side effects

Common side effects	What to do
<p>Injection site reactions:</p> <ul style="list-style-type: none"> Itching Bruising Redness Bleeding, swelling, pain or hardness around the injection site. <p>Infections:</p> <ul style="list-style-type: none"> Cold Sinus infections <p>Allergic reactions</p> <p>Symptoms of an allergic reaction may include:</p> <ul style="list-style-type: none"> wheezing, shortness of breath, difficulty breathing, or a tight feeling in your chest, swelling of the face, lips, tongue or other parts of the body, rash, itching, hives or flushed red skin, dizziness or light-headedness. <p>Other:</p> <ul style="list-style-type: none"> Headaches Fever 	<p>Speak to your doctor if you have any of these common side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Infections:</p> <ul style="list-style-type: none"> Tuberculosis Blood poisoning (sepsis) Signs of an infection such as fever, chills, mouth ulcers or sore throat <p>Lung disease:</p> <ul style="list-style-type: none"> Breathlessness during exercise or a dry cough <p>Soft tissue infections:</p>	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

<ul style="list-style-type: none"> Bumps or sores that do not heal, are swollen, red or have pus <p>Nervous system disorders:</p> <ul style="list-style-type: none"> Seizures, numbness or tingling throughout your body, weakness in your arms and/or legs and dizziness, or problems with your eyesight. <p>Inflammation:</p> <ul style="list-style-type: none"> Spinal cord Inner eye Blood vessels in the skin or lymph glands Signs of inflammatory bowel such as diarrhoea or mucus or blood in your stools, stomach cramps, fever or weight loss Signs your kidneys may not be functioning properly, including urinating less often, pink/dark brown, foamy/bubbly urine, swelling of the face, hands, feet and abdomen, and high blood pressure. <p>Allergic reaction:</p> <ul style="list-style-type: none"> Swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, or hives. <p>Lupus or lupus-like syndrome:</p> <ul style="list-style-type: none"> Weight changes, persistent rash, fever, joint or muscle pain or fatigue <p>Immune system disorders:</p> <ul style="list-style-type: none"> Skin rash, blisters and ulcers on the skin, in the mouth or airways <p>Blood disorders:</p> <ul style="list-style-type: none"> Tiredness, headaches, shortness of breath when exercising, dizziness, paleness, nose bleeds, unusual bleeding or bruising or more frequent infections. <p>Heart failure:</p> <ul style="list-style-type: none"> Shortness of breath, persistent cough, difficulty exercising, fast or irregular heartbeat, swelling in the legs or feet, tiredness and weakness. 	
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There have been reports of some types of cancer developing in patients using etanercept and other TNF blocking medicines. These include skin cancers, cancers that affect the lymph system called lymphoma and Kaposi's sarcoma (which also affects the organs, skin, mouth, nose or throat), or affect the blood system called

leukaemia. The role of etanercept in the development of cancer is not known.

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 or to Medsafe at <https://pophealth.my.site.com/carmreportnz/s/>. 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 Erelzi contains

Active ingredient (main ingredient)	etanercept (rch)
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• citric acid• sodium citrate dihydrate• sodium chloride• sucrose• lysine hydrochloride• sodium hydroxide and/or hydrochloric acid (for pH adjustment)• water for injection
Potential allergens	N/A

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

What Erelzi looks like

Erelzi solution for injection is supplied in single use, pre-filled syringes comprising a clear glass barrel with a fixed stainless steel needle, rubber plunger stopper and needle shield. The pre-filled syringes are assembled with a needle guard or auto-injector for subcutaneous (sc) administration:

- ERELZI 25 mg etanercept (in 0.5 mL) solution for injection: packs of 1, 2, 4 or 12 pre-filled syringes assembled with needle guard. (Aust R 281783)
- ERELZI 50 mg etanercept (in 1 mL) solution for injection: packs of 1, 2, 4 or 12 pre-filled syringes assembled with needle guard. (Aust R 281784)
- ERELZI 50 mg etanercept (in 1 mL) solution for injection: packs of 1, 2, 4 or 12 pre-filled syringes in auto-injectors. (Aust R 281780)

Not all pack sizes and/or presentations may be available in Australia and New Zealand.

Who distributes Erelzi

Erelzi is distributed in Australia by:

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia
Tel 1800 726 369

Erelzi is distributed in New Zealand by:

Sandoz New Zealand Limited
12 Madden Street
Auckland 1010
New Zealand
Tel: 0800 726 369

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