

# Enbrel®

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## 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 Enbrel?

Enbrel contains the active ingredient etanercept. Enbrel 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 Enbrel?](#) in the full CMI.

### 2. What should I know before I use Enbrel?

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 Enbrel?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with Enbrel 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 Enbrel?**

- Enbrel 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.
- Enbrel is injected under the skin and is for single use in one patient only. Refer to Instructions for Use provided in the pack.
- Enbrel dose-dispenser cartridges are intended for use with the SmartClic injection device.

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

## 5. What should I know while using Enbrel?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor or dentist you visit that you are using Enbrel.</li><li>• Tell your doctor if you have latex allergies.</li><li>• Ensure children are up to date with vaccinations prior to starting Enbrel.</li><li>• Tell your doctor if you are at risk of blood poisoning or infections, such as leg ulcers.</li><li>• Contraception is recommended to avoid becoming pregnant during Enbrel therapy and for 3 weeks after discontinuation of Enbrel therapy. Inform your doctor immediately if you are planning pregnancy or are pregnant.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using this medicine suddenly, unless advised by your doctor.</li></ul>

	<ul style="list-style-type: none"> <li>• Do not shake the solution of Enbrel after you have added the sterile water for injection.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Keep Enbrel in the fridge between 2°C and 8°C. Do not freeze.</li> <li>• Store Enbrel in the cartons to protect from light.</li> <li>• Enbrel powder for injection must be discarded 6 hours after preparation into a solution.</li> </ul>

For more information, see Section [5. What should I know while using Enbrel?](#) 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.



# Enbrel®

**Active ingredient(s):** *etanercept*

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## **Consumer Medicine Information (CMI)**

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

**Where to find information in this leaflet:**

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

## **1. Why am I using Enbrel?**

**Enbrel 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.

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

## **2. What should I know before I use Enbrel?**

### **Warnings**

#### **Do not use Enbrel if:**

1. you are allergic to etanercept, latex or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

2. 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. Enbrel 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.

3. you are currently taking anakinra or other similar medicines known as Interleukin-1 antagonists.
4. the packaging is torn or shows signs of tampering
5. the expiry date printed on the pack has passed.

If you use Enbrel 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:
  - latex (the needle cover of the pre-filled syringe, dose-dispenser cartridge, auto-injector and the rubber closure of the diluent syringe (vial presentation) contain dry natural rubber),
  - 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 Enbrel in pregnant women are not well understood, therefore Enbrel should only be used during pregnancy if clearly needed.

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

If you become pregnant while using Enbrel, 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 Enbrel can pass into breast milk. If you are breastfeeding, you should discuss the use of Enbrel and the options available with your doctor.

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

## **Use in Children**

- Enbrel 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 Enbrel.

Live vaccines, such as oral polio vaccine, should not be given while receiving Enbrel.

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

Enbrel 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 Enbrel and affect how it works.**

**Medicines that increase risk of side effects when used with Enbrel:**

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

**Medicines that Enbrel 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 Enbrel.**

## **4. How do I use Enbrel?**

Your doctor will tell you how to inject Enbrel. 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 use**

#### **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 Enbrel.
- If you are being treated for psoriasis, your doctor may prescribe a higher dose of Enbrel when you first begin your treatment.
- If you are being treated for nr-AxSpA and Enbrel 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 Enbrel 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 preparing and measuring the appropriate dose for your child.

- For juvenile idiopathic arthritis, the recommended dose is 0.8 mg of Enbrel per kg bodyweight (up to a maximum of 50 mg) given once weekly. Enbrel may also be given twice weekly at a dose of 0.4 mg of Enbrel per kg bodyweight (up to a maximum of 25 mg).
- For psoriasis patients, the recommended dose is 0.8 mg of Enbrel per kg bodyweight (up to a maximum of 50 mg) given once weekly. If Enbrel has no effect on the child's condition after 12 weeks, your doctor may tell you to stop using this medicine.

## **When to use Enbrel**

- Enbrel 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 use Enbrel**

Your doctor will supervise and advise you on how to use Enbrel when you first start. If your doctor thinks it is appropriate, they can train you on how to self-inject Enbrel.

Enbrel should be administered according to the instructions provided in the Instructions for Use leaflet included with the medicine and the user manual provided with the SmartClic injection device for the dose-dispenser cartridge.

### **Powder for injection:**

- Enbrel powder for injection contains no additives that would prevent the growth of bacteria once the

powder is dissolved. For this reason, the vial should not be stored for more than 6 hours after dissolving the powder with the diluent provided.

**Solution for injection only:**

- After allowing the Enbrel solution to reach room temperature (approximately 15 to 30 minutes), immediate use is recommended.
- Each vial or syringe of Enbrel is for single use only, in one patient only. Discard any residue.

**Dose-dispenser cartridge for use in the SmartClic injection device only:**

- After allowing the Enbrel dose-dispenser cartridge to reach room temperature (approximately 30 minutes), immediate use is recommended.
- Each dose-dispenser cartridge (for use in SmartClic injection device) is for single use in one patient only.
- The SmartClic injection device is supplied separately by the doctor who prescribed Enbrel to you, or by contacting Pfizer ([www.enbrel.com.au](http://www.enbrel.com.au) or call 1800 362 735).

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you are injecting Enbrel yourself, you must follow the detailed instructions provided in the leaflet inside the pack.

Enbrel is injected under the skin. When using the syringes provided with the Enbrel vial, pre-filled syringe or dose-dispenser cartridge presentations, it is important that you do not pull back on the plunger. Enbrel can be injected by your doctor, nurse, carer or by yourself.

When you have finished injecting Enbrel, discard the needle and syringe into a sharps container.

If you do not understand the instructions for injecting Enbrel 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 Enbrel injection.

You should continue to inject Enbrel for as long as your doctor recommends.

Never inject more than the dose recommended by your doctor.

If you feel that the effect of Enbrel is too strong or too weak, talk to your doctor or pharmacist.

## **If you forget to use Enbrel**

Enbrel 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 Enbrel**

If you think that you have used too much Enbrel, 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.**

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 Enbrel. Ask your doctor if you have any concerns.



## **5. What should I know while using Enbrel?**

### **Things you should do**

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

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

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

### **Call your doctor straight away if you:**

- Have or develop any serious infection while using Enbrel. Do not inject any more Enbrel 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 Enbrel.

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

### **Things you should not do**

- Do not stop using this medicine suddenly or lower the dosage without checking with your doctor.

- Do not shake the solution of Enbrel after you have added the sterile water for injection. Shaking the solution will cause it to froth (create lots of bubbles). This may affect the medicine so that it may not work.
- Do not stop using Enbrel because you are feeling better, unless your doctor advises you to. Your condition may flare up if you reduce the dose or stop using Enbrel.
- Do not give Enbrel to anyone else even if they have the same condition as you.
- Do not use Enbrel to treat any other complaints unless your doctor tells you to.
- Do not stop using Enbrel, or lower the dosage, without checking with your doctor.

## **Driving or using machines**

It is not known whether Enbrel causes dizziness or drowsiness.

## **Drinking alcohol**

No information is available.

## **Looking after your medicine**

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

Keep Enbrel in a refrigerator where the temperature stays between 2°C and 8°C.

Keep it 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 Enbrel pre-filled syringes, auto-injectors and dose-dispenser cartridges in their cartons to protect them from light.

Heat and dampness can destroy some medicines.

If it is not possible to store Enbrel 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 Enbrel 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 Enbrel 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 Enbrel, contact Pfizer Medical Information on 1800 362 735.

Do not use this medicine after the expiry date.

**Keep it where young children cannot reach it.**

## **When to discard your medicine**

Powder for injection only:

Dispose of any Enbrel solution that has been prepared more than 6 hours ago, but not used.

Enbrel powder in vials does not contain a preservative, therefore, once the powder is mixed, the solution may spoil after 6 hours.

## 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.

## 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
<b>Injection site reactions:</b> <ul style="list-style-type: none"><li>• Itching</li><li>• Bruising</li><li>• Redness</li><li>• Bleeding, swelling, pain or hardness around the injection site.</li></ul> <b>Infections:</b>	<b>Speak to your doctor if you have any of these common side effects and they worry you.</b>

<b>Common side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• Cold</li> <li>• Sinus infections</li> <li>• <b>Allergic reactions</b> Symptoms of an allergic reaction may include: <ul style="list-style-type: none"> <li>• wheezing, shortness of breath, difficulty breathing, or a tight feeling in your chest,</li> <li>• swelling of the face, lips, tongue or other parts of the body,</li> <li>• rash, itching, hives or flushed red skin,</li> <li>• dizziness or light-headedness.</li> </ul> </li> </ul> <p><b>Other:</b></p> <ul style="list-style-type: none"> <li>• Headaches</li> <li>• Fever</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Infections:</b></p> <ul style="list-style-type: none"> <li>• Tuberculosis</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency</b></p>

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• Blood poisoning (sepsis)</li> <li>• Signs of an infection such as fever, chills, mouth ulcers or sore throat</li> </ul> <p><b>Lung disease:</b></p> <ul style="list-style-type: none"> <li>• Breathlessness during exercise or a dry cough</li> </ul> <p><b>Soft tissue infections:</b></p> <ul style="list-style-type: none"> <li>• Bumps or sores that do not heal, are swollen, red or have pus</li> </ul> <p><b>Nervous system disorders:</b></p> <ul style="list-style-type: none"> <li>• Seizures, numbness or tingling throughout your body, weakness in your arms and/or legs and dizziness, or problems with your eyesight.</li> </ul> <p><b>Inflammation:</b></p> <ul style="list-style-type: none"> <li>• Spinal cord</li> <li>• Inner eye</li> <li>• Blood vessels in the skin or lymph glands</li> <li>• Signs of inflammatory bowel such as diarrhoea</li> </ul>	<p><b>Department at your nearest hospital if you notice any of these serious side effects.</b></p>

Serious side effects	What to do
<p>or mucus or blood in your stools, stomach cramps, fever or weight loss.</p> <p><b>Allergic reaction:</b></p> <ul style="list-style-type: none"> <li>• Swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, or hives.</li> </ul> <p><b>Lupus or lupus-like syndrome:</b></p> <ul style="list-style-type: none"> <li>• Weight changes, persistent rash, fever, joint or muscle pain or fatigue</li> </ul> <p><b>Immune system disorders:</b></p> <ul style="list-style-type: none"> <li>• Skin rash, blisters and ulcers on the skin, in the mouth or airways</li> </ul> <p><b>Blood disorders:</b></p> <ul style="list-style-type: none"> <li>• Tiredness, headaches, shortness of breath when exercising, dizziness, paleness, nose bleeds, unusual</li> </ul>	

Serious side effects	What to do
<p>bleeding or bruising or more frequent infections.</p> <p><b>Heart failure:</b></p> <ul style="list-style-type: none"> <li>• shortness of breath, persistent cough, difficulty exercising, fast or irregular heartbeat, swelling in the legs or feet, tiredness and weakness.</li> </ul>	

There have been reports of some types of cancer developing in patients using Enbrel 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 Enbrel 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](http://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 Enbrel contains**

#### **Powder for injection**

<b>Active ingredient (main ingredient)</b>	Etanercept
<b>Other ingredients (inactive ingredients)</b>	Mannitol Trometamol Sucrose

#### **Solution for injection**

Prefilled syringe, Auto-injector and Dose-dispenser cartridge

<b>Active ingredient</b>	Etanercept
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<b>(main ingredient)</b>	
<b>Other ingredients (inactive ingredients)</b>	Sucrose Sodium chloride Arginine hydrochloride Monobasic sodium phosphate dihydrate Dibasic sodium phosphate dihydrate Water

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

**Enbrel powder for injection and solution for injection do not contain lactose, gluten, tartrazine or any other azo dyes.**

## **What Enbrel looks like**

### **Powder for injection:**

Enbrel powder for injection is supplied as a pack containing:

- Four single dose glass vials of Enbrel powder. Each vial of Enbrel contains 25 mg of the active ingredient, etanercept.
- Four pre-filled glass syringes of sterile water for injections.

The rubber closure of the diluent syringe contains dry natural rubber (a derivative of latex). The powder must be dissolved in 1 mL of the sterile water for injections before use.

- Four sterile vial adaptors and four sterile needles.

The vial adaptor is for delivering the water into the Enbrel vial. It should be replaced with a needle for injection after the Enbrel solution has been drawn up into the syringe.

(AUST R 90456)

### **Pre-filled Syringe (Solution for injection):**

Enbrel Pre-filled Syringe is supplied in a kit containing:

- Four single-dose pre-filled glass syringes containing Enbrel solution.

Each syringe contains 50 mg of etanercept in 1 mL of Enbrel solution. The needle cover of the pre-filled syringe presentation contains dry natural rubber (a derivative of latex).

- Four alcohol swabs.

(AUST R 124422)

### **Auto-injector (Solution for injection)**

Enbrel Auto-injector is supplied in a kit containing:

- Either one or four single-dose pre-filled glass syringes, each housed in a plastic Auto-injector.

Each syringe contains 50 mg of etanercept in 1 mL of Enbrel solution. The needle cap of the Auto-injector contains dry natural rubber (a derivative of latex).

- Two or four alcohol swabs are also provided in the kit.  
(AUST R 157622)

**Dose-dispenser cartridge (Solution for injection) for use with the SmartClic injection device (supplied separately).**

Enbrel dose-dispenser cartridge is supplied in a pack containing:

- Either one or four single-use dose-dispenser cartridges.

Each cartridge contains either 25 mg of etanercept in 0.5 mL of Enbrel solution or 50 mg of etanercept in 1 mL of Enbrel solution. The needle cap of the dose-dispenser cartridge contains dry natural rubber (a derivative of latex).

- Two or eight alcohol swabs are also provided in the pack.

(AUST R 352090 and 352091)

Not all presentations may be marketed.

## **Who distributes Enbrel**

Enbrel is supplied in Australia by:

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

[www.pfizermedinfo.com.au](http://www.pfizermedinfo.com.au)

Administration kit is prepared by:

Pfizer Manufacturing Belgium

Rijksweg 12

Puurs, Belgium

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