

ENBREL®

Etanercept Powder and Solvent for Solution for Injection;
Etanercept Solution for Injection (pre-filled syringe);
Etanercept Solution for Injection (Auto-injector)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Enbrel.

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 taking Enbrel against the benefits this medicine is expected to have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What Enbrel is used for

Enbrel is used in the treatment of:

- rheumatoid arthritis
- juvenile idiopathic arthritis
- ankylosing spondylitis
- non-radiographic axial spondyloarthritis (nr-AxSpA)
- psoriatic arthritis
- plaque psoriasis.

Tumour necrosis factor (TNF) is a naturally occurring chemical messenger in your bloodstream. TNF plays a role in causing pain and swelling in the joints. Enbrel is a biotechnology-derived protein that works by binding to TNF and preventing it from acting. This reduces the pain and swelling of rheumatoid arthritis and psoriasis, helps to treat the skin lesions of psoriasis and psoriatic arthritis, and improves the condition of patients with ankylosing spondylitis, 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.

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.

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

Enbrel is not addictive.

Before you use Enbrel

When you must not use it

Do not use Enbrel if:

- 1. You have an allergy to Enbrel or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include 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.

- 2. You have, or are at risk of developing, sepsis (blood poisoning), or long-term or localised infection (for example, leg ulcer).**

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 (EXP) 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.

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

Before you use it

Tell your doctor if:

1. You have any allergies to:

- Latex, as the needle cover of the pre-filled syringe and 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.

2. 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. 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.

3. You are breast-feeding or plan to breast-feed.

Enbrel passes through breast milk. Therefore, if you are breast-feeding, you should discuss with your doctor whether to stop breast-feeding or stop using Enbrel.

4. You have or have had any other medical conditions, especially the following:

- 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
- Chicken pox or have been recently exposed to chickenpox.

Make sure that children are up to date with all vaccinations (including chicken pox) before they start treatment with Enbrel.

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

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

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 or health food shop.

Some medicines may affect the way others work. Your doctor or pharmacist will be able to tell you what to do when using Enbrel with other medicines. Enbrel may interact with other medicines such as:

- Abatacept, sulfasalazine or Interleukin-1 antagonists such as anakinra. These medicines are used to treat rheumatoid arthritis and other inflammatory diseases
- Cyclophosphamide, a medicine used to treat cancer or prevent transplant rejection
- Some vaccines

- Digoxin, a medicine used to improve the strength and efficiency of the heart, or to control the rate and rhythm of the heartbeat
- Warfarin, a medicine used to thin the blood and prevent blood clots
- Medicines used to treat diabetes.

How to use Enbrel

Powder for injection only:

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.

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 or pre-filled syringe 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.

How much to use

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.

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.

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.

How long to take it

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 take it

If you forget to give yourself or your child an injection, 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 more than 48 hours since the last dose was due, wait for the next scheduled dose.

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

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

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (tel 13 11 26) for advice or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have used too much Enbrel. 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.

While you are using Enbrel

Things you must 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.

If you have or develop any serious infection while using Enbrel, do not inject any more Enbrel and contact your doctor immediately.

Seek medical advice immediately if you 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.

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

It is not known whether Enbrel causes dizziness or drowsiness.

Things you must not do

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 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.

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.

Side effects

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

Like other medicines, Enbrel can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention. The most common side effects with Enbrel are injection site reactions, infections, allergic reactions, itching, rash and fever. Please see below for more detail.

Ask your doctor or pharmacist to answer any questions you may have.

Injection site reactions

The most common side effect is a mild reaction in the area where Enbrel was injected, including:

- Itching
- Bruising
- Redness
- Bleeding, swelling, pain or hardness around the injection site.

These reactions generally do not occur as often after the first month of treatment.

If you are concerned about injection site reactions, contact your doctor or pharmacist.

When injecting Enbrel, some people have developed a reaction to an injection site used before.

Infections

Infections, including colds and sinus infections, are very common.

Serious infections may occur including tuberculosis and blood poisoning.

Tell your doctor immediately if you notice any of the following:

- Signs of an infection such as fever, chills, mouth ulcers or sore throat
- Signs of lung disease such as breathlessness during exercise or a dry cough
- Signs of soft tissue infections such as bumps or sores that do not heal, are swollen, red or have pus
- Signs of nervous system disorders such as seizures, numbness or tingling throughout your body, weakness in your arms and/or legs and dizziness, or problems with your eyesight
- Inflammation of the spinal cord
- Inflammation of the inner eye
- Inflammation of blood vessels in the skin or lymph glands
- Signs of inflammatory bowel disease such as diarrhoea or mucus or blood in your stools, stomach cramps, fever or weight loss
- Signs of an allergic reaction such as swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, or hives
- Signs of lupus or lupus-like syndrome, such as weight changes, persistent rash, fever, joint or muscle pain, or fatigue

- Other signs of immune system disorders such as skin rash, blisters and ulcers on the skin, in the mouth or airways
- Signs of a blood disorder such as tiredness, headaches, shortness of breath when exercising, dizziness, paleness, nose bleeds, unusual bleeding or bruising or more frequent infections
- Signs of heart failure such as shortness of breath, persistent cough, difficulty exercising, fast or irregular heartbeat, swelling in the legs or feet, tiredness and weakness.

These may be very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you unwell.

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.

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

After using Enbrel

Storage

Keep Enbrel where children cannot reach it.

Keep Enbrel in a refrigerator where the temperature stays between 2°C and 8°C. Do not freeze. Do not store Enbrel or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills. Enbrel pre-filled syringes and Auto-injectors should be stored 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.

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.

For additional advice on storing Enbrel, contact Pfizer Medical Information on 1800 362 735.

Disposal

Ask your pharmacist how to dispose of medicines no longer required.

Product description

What it 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. The pack also includes 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 are also supplied. 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.

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 are also provided in the kit.

Auto-injector (Solution for injection)

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

Ingredients

Powder for injection:

Enbrel powder for injection contains 25 mg of the active ingredient etanercept. Enbrel also contains mannitol, trometamol and sucrose.

Solution for injection:

Enbrel solution for injection contains 50 mg of the active ingredient etanercept. The Enbrel solution also contains sucrose, sodium chloride, arginine hydrochloride, monobasic sodium phosphate dihydrate, dibasic sodium phosphate dihydrate and water.

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

Australian Patient Support Program details

Your ENBREL Experience is a complimentary support program offered for people taking Enbrel. The program is designed based on feedback from many people already taking Enbrel, and nurses who work with them. Call 1800 ENBREL (1800 362 735) or visit www.1800ENBREL.com.au

Supplier

Enbrel is supplied in Australia by:

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizer.com.au

Administration kit was prepared by:

Pfizer Manufacturing Belgium

Rijksweg 12

Puurs, Belgium

Australian Registration Number

25 mg powder with diluent kit: AUST R 90456

50 mg solution for injection kit: AUST R 124422

50 mg Auto-injector solution for injection: AUST R 157622

Date of preparation

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