

BRENZYS® Etanercept Solution for Injection (pre-filled syringe)

BRENZYS® Etanercept Solution for Injection (Auto-injector)

Each syringe or auto-injector contains etanercept 50 mg

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Brenzys.

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 Brenzys 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 Brenzys is used for

Brenzys is used in adults for the treatment of:

- rheumatoid 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. Brenzys 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 and nr-AxSpA.

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

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

Brenzys is not addictive.

Brenzys is not indicated for use in children less than 18 years of age. Other etanercept products are available for use in children.

Before you use Brenzys

When you must not use it

Do not use Brenzys if:

1. **You have an allergy to Brenzys 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. Brenzys 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, or other biological medicines such as anti-TNF drugs, tocilizumab or abatacept.**
4. **The packaging is torn or shows signs of tampering.**
5. **The expiry date (EXP) printed on the pack has passed.**

If you use Brenzys 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:**

- Any other medicines
- Any other substances, such as foods, preservatives or dyes.

2. **You are pregnant or intend to become pregnant.**

The effects of Brenzys in pregnant women are not well understood, therefore Brenzys should only be used during pregnancy if clearly needed. If you become pregnant while using Brenzys, 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.**

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

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.

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

Ensure that children are up to date with all vaccinations (including chicken pox)

before they start treatment with etanercept.

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

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 Brenzys with other medicines. Brenzys 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 Brenzys

After allowing the Brenzys syringe or Auto-injector to reach room temperature (approximately 30 minutes), immediate use is recommended.

Each syringe or Auto-injector of Brenzys 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 Brenzys yourself, you must follow the detailed instructions provided in the leaflet inside the pack.

Brenzys is injected under the skin. When using the syringe or Auto-injector, it is important that you do not pull back on the plunger. Brenzys can be injected by your doctor, nurse, carer or by yourself.

When you have finished injecting Brenzys, discard the syringe or Auto-injector into a sharps container.

If you do not understand the instructions for injecting Brenzys 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 should have an Brenzys injection.

How much to use

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

Adults

The recommended dose for adults is 50 mg per week, injected under the skin. Your

doctor may determine a different frequency at which to inject Brenzys. If you are being treated for psoriasis, your doctor may prescribe a higher dose of Brenzys when you first begin your treatment. If you are being treated for nr-AxSpA and Brenzys has no effect on your condition within 12 weeks, your doctor may tell you to stop using this medicine.

Children

Brenzys is not indicated for use in children less than 18 years of age. Other etanercept products are available for use in children.

How long to take it

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

Never inject more than the dose recommended by your doctor.

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

If you forget to take it

If you forget to give yourself 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 Brenzys. 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 Brenzys. Ask your doctor if you have any concerns.

While you are using Brenzys

Things you must do

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

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

If you have or develop any serious infection while using Brenzys, do not inject any more Brenzys 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 Brenzys.

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

It is not known whether Brenzys causes dizziness or drowsiness.

Things you must not do

Do not shake the Brenzys syringe or Auto-injector.

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

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

Do not stop using Brenzys, or lower the dosage, without checking with your doctor.

Do not stop using Brenzys because you are feeling better, unless your doctor advises you to.

Your condition may flare up if you reduce the dose or stop using Brenzys.

Side effects

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

Like other medicines, Brenzys 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 Brenzys 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 Brenzys 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 Brenzys, 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 eye sight
- 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 Brenzys 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 Brenzys 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 Brenzys

Storage

Keep Brenzys where children cannot reach it.

Keep Brenzys in a refrigerator where the temperature stays between 2°C and 8°C. Do not freeze. Do not store Brenzys or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills. Brenzys 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 Brenzys 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 Brenzys 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 Brenzys if it has been exposed to high temperatures, or has been out of the refrigerator for more than 4 weeks.

Disposal

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

Product description

What it looks like

Pre-filled Syringe (Solution for injection):

Brenzys Pre-filled Syringe is supplied in a carton containing four single-use pre-filled glass syringes containing Brenzys solution. Each syringe contains 50 mg of etanercept in 1 mL of Brenzys solution.

Auto-injector (Solution for injection)

The Brenzys Auto-injector is supplied in a carton containing either one or four single-use pre-filled glass syringes, each housed in a plastic Auto-injector. Each syringe contains 50 mg of etanercept in 1 mL of Brenzys solution.

Ingredients

Solution for injection:

Brenzys solution for injection contains 50 mg of the active ingredient etanercept (rch). The Brenzys solution also contains sucrose, sodium chloride, sodium phosphate monobasic monohydrate, sodium phosphate dibasic (heptahydrate) and water.

Sponsor

Brenzys is supplied by:

Sponsor:

SAMSUNG BIOEPIS AU PTY LTD
Level 16, 201 Elizabeth Street,
Sydney NSW 2000, Australia

Distributor:

Organon Pharma Pty Limited Building A, 26
Talavera Road, Macquarie Park, NSW 2113,
Australia

Australian Registration Number:

50 mg pre-filled syringe solution for
injection: AUST R 245252

50 mg Auto-injector solution for injection:
AUST R 245253

Date of preparation

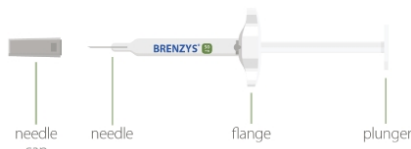
This leaflet was prepared in March 2022.

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Instructions for Use

The following instructions are for preparing and giving a dose of BRENZYS® using a single-use pre-filled syringe.

YOUR BRENZYS® PRE-FILLED SYRINGE



STEP 1: GATHER SUPPLIES

- Place your syringe and unopened alcohol swabs on a clean, dry surface.
- Remember to wash your hands!
- Don't remove the cap just yet!



Step 2: WAIT 30 MINUTES

- Wait approximately 30 minutes for your syringe to warm-up to room temperature, which helps reduce your pain during injection.
- Don't remove the cap just yet!



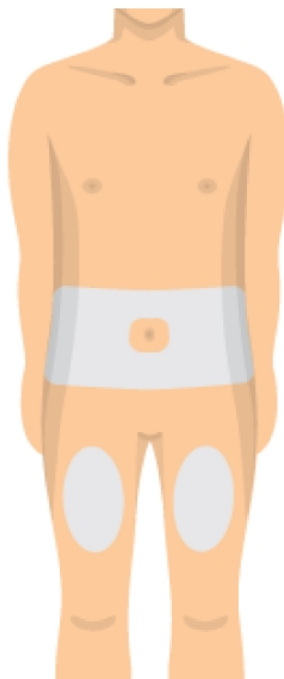
Step 3: INSPECT MEDICINE & DATE

- Always make sure your medicine hasn't expired.
- The medicine should be clear or slightly opalescent, colourless or pale yellow, and may contain small white or almost transparent particles of protein.
- You may see an air bubble, and that's okay.
- Don't remove the cap just yet!



Step 4: CHOOSE SITE & CLEAN SKIN

- Choose an injection site on your body.
- Your abdomen or thighs are best.
- Wipe your skin at the injection site with an alcohol swab.
- Avoid skin that's sore, bruised, scarred, scaly or has red patches.



Step 5: REMOVE SYRINGE CAP

- Carefully remove the needle cap.



Step 6: PINCH SKIN & INSERT NEEDLE

- Gently pinch your skin, and carefully insert the needle.



Step 7: PUSH PLUNGER ALL THE WAY

- Hold the syringe steady and press the plunger all the way down.



Step 8: REMOVE SYRINGE & DISPOSE

- Pull the syringe away from your skin and dispose of it in a sharps container.
- Don't recap or reuse your needle.



Instructions for Use

The following instructions are for preparing and giving a dose of BRENZYS® using a single-use auto-injector.

YOUR BRENZYS® AUTO-INJECTOR



Step 1: GATHER SUPPLIES

- Place your auto-injector and unopened alcohol swabs on a clean, dry surface.
- Remember to wash your hands!
- Don't remove the cap just yet!



Step 2: WAIT 30 MINUTES

- Wait approximately 30 minutes for your auto-injector to warm-up to room temperature, which helps reduce your pain during injection.
- Don't remove the cap just yet!



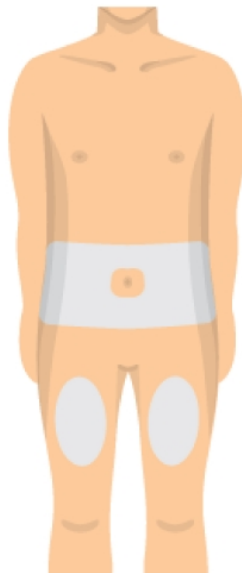
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- The medicine should be clear or slightly opalescent, colourless or pale yellow, and may contain small white or almost transparent particles of protein.
- You may see an air bubble, and that's okay.
- Don't remove the cap just yet!



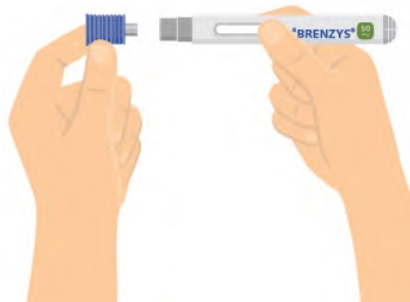
Step 4: CHOOSE SITE & CLEAN SKIN

- Choose an injection site on your body.
- Your abdomen or thighs are best.
- Wipe your skin at the injection site with an alcohol swab.
- Avoid skin that's sore, bruised, scarred, scaly or has red patches.



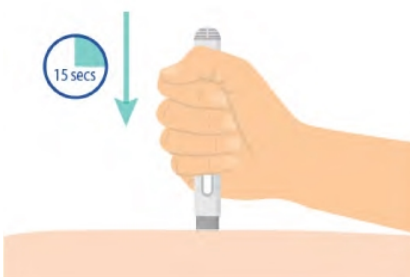
Step 5: REMOVE THE BLUE NEEDLE CAP

- Carefully remove the blue needle cap with a metal center from the auto-injector.



Step 6: PLACE GRAY NEEDLE SHIELD, PRESS DOWN, AND HOLD 15 SECONDS

- Place the gray needle shield straight on your skin, and push the entire auto-injector down firmly to start the injection.
- When you push down, the injection starts.
- You may hear a click.



Step 7: AFTER 15 SECONDS, REMOVE AUTO-INJECTOR

- Hold the auto-injector against your skin.
- After 15 seconds, remove the auto-injector from the injection site.
- The medication window will change to yellow once the injection is completed.
- You may hear a second click.



Step 8: CONFIRM COMPLETION & DISPOSE AUTO-INJECTOR

- Confirm that the medication window is yellow.
- Discard your auto-injector in a sharps container.
- As per illustration a small grey band may still be visible.
- If the window isn't yellow, you may not have received your full dose.

