

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.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using Xembify®?

Xembify® contains the active ingredient normal immunoglobulin . Xembify® is used to help your body fight infections.

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

2. What should I know before I use Xembify®?

Do not use if you have ever had an allergic reaction to normal immunoglobulin 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 Xembify®?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Xembify® 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 Xembify®?

- The recommended dose and dosing schedule are established by your doctor.
- Xembify® has to be infused under the skin (subcutaneous or SC administration).

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

5. What should I know while using Xembify®?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Xembify®• Have routine blood tests to measure the level of immunoglobulin in your blood.
Things you should not do	<ul style="list-style-type: none">• Do not change the dose or the time interval to the next dose without talking to your doctor first.• Do not use this medicine after the expiry date which is stated on the label and carton• Do not use this medicine if you notice it is cloudy, discoloured, turbid, or if it has been frozen.
Driving or using machines	<ul style="list-style-type: none">• Your ability to drive and operate machines may be impaired by some adverse reactions associated with Xembify®.
Looking after your medicine	<ul style="list-style-type: none">• Store in a refrigerator (2°C to 8°C). Do not freeze. Additionally, Xembify® may be stored at room temperature (25°C) for up to 6 months any time prior to the expiration date.• Keep the vial in the outer carton in order to protect from light.

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

6. Are there any side effects?

Like all medicines, this medicine can cause side effects, although not everybody gets them, such as chills, headache, dizziness, fever, vomiting, allergic reactions, feeling sick (nausea), joint pain, low blood pressure and moderate low back pain.

Rarely normal immunoglobulin may cause a sudden fall in blood pressure and, in isolated cases, anaphylactic shock, even when the patient has shown no hypersensitivity to previous administration.

Local reactions at infusion sites: swelling, soreness, redness, induration, local heat, itching, bruising and rash, may frequently occur.

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.



This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

Xembify® (zem-be-fai)

Active ingredient(s): Normal Immunoglobulin

Consumer Medicine Information (CMI)

This leaflet provides important information about using Xembify®. **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 Xembify®.**

Where to find information in this leaflet:

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

1. Why am I using Xembify®?

Xembify® contains the active ingredient normal immunoglobulin. Xembify® is a 20% solution that you inject into the fatty layer under the skin (subcutaneous injection). Xembify® contains human immunoglobulins (antibodies) to help your body fight infections.

You are taking Xembify® because you have abnormally low levels of antibodies due to a medical condition called an immune deficiency. Xembify® injections restore antibodies in your blood to normal levels.

This medicine is for adults, children and adolescents (0 - 18 years) who do not have sufficient antibodies.

2. What should I know before I use Xembify®?

Warnings

Do not use Xembify®:

- if you are allergic to normal immunoglobulin, or any of the ingredients listed at the end of this leaflet.
- if you have antibodies against immunoglobulin A (IgA) in your blood. This may occur if you have IgA deficiency. Since Xembify® contains IgA, you might have an allergic reaction.
- by injecting it into a blood vessel (intravenously).

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

Check with your doctor if you:

- have any other medical conditions.
- take any medicines for any other condition.
- have ever experienced any side effects from an immunoglobulin or from any of the ingredients.

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.

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

Xembify® has not been studied in pregnant women or breast-feeding women

Elderly patients

If you are 65 and over, you may be at increased risk for thrombosis (blood clot). Tell your doctor right away if you have any of the following symptoms of a blood clot in a blood vessel: shortness of breath; chest pains; pain and swelling of an arm or leg; or weakness or numbness on one side of your body.

Tell your doctor if:

you have a medical history of heart disease, blood vessel disease, a blood clot in a blood vessel (such as a stroke, heart attack, or pulmonary embolism), thick blood, diabetes mellitus, or if you have been immobile for some time. You may have a greater risk of developing a blood clot after infusion of Xembify®.

Medicine Specific Information

Xembify® may interfere with some blood tests. Always tell your doctor that you are being treated with Xembify® prior to any blood test.

Xembify® is manufactured from pooled plasma collected from healthy donors. The risk that Xembify could infect you with blood-borne viruses is reduced because:

- plasma donors must meet strict health standards;

- plasma donations are tested for a panel of infectious viruses and those that test positive are rejected; and
- the manufacturing process has been demonstrated by laboratory studies to have significant capacity to remove or kill a diverse panel of infectious viruses.

However, even with these multiple assurances, it is not possible to completely eliminate risk of viral infection from Xembify® treatment.

It is strongly recommended that every time you inject a dose of Xembify®, write the name and lot number (look on the vial label and carton) in your patient record.

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.

Never mix any other medicines with Xembify®.

If you are going to be vaccinated, tell the doctor that you are being treated with Xembify®. Xembify® may interfere with some vaccines (live virus vaccines) such as measles, mumps, rubella and chicken pox. You may have to wait up to 3 months after receiving Xembify before being vaccinated. For measles vaccine, you may have to wait for up to 1 year.

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

4. How do I use Xembify®?

How much to take / use

- Your doctor will calculate the correct dose for you based on your body weight, any previous treatment you may have received and your response to treatment.
- Your first dose may be what is called a “loading dose” which is meant to rapidly increase the immunoglobulin levels in your blood and will be infused by your doctor.
- Your doctor may adjust your dose depending on your response to treatment.
- Do not change your dose without talking to your doctor first.
- If you think you should receive a different dose talk to your doctor first.

When to take / use Xembify®

- You will be given a regular schedule to infuse Xembify®.
- Follow the schedule of infusions of Xembify® set by your doctor.
- Do not change this schedule without talking to your doctor first.

- If you need to modify your dosing schedule, talk to your doctor first. Contact your doctor if you get off schedule or miss a dose.
- Keep all appointments for routine blood tests. They are used to measure the level of immunoglobulin in your blood. Discuss the schedule with your doctor.
- Follow the instructions provided and use Xembify® until your doctor tells you to stop.

How to use Xembify®

Your doctor or nurse will first infuse Xembify slowly, and carefully monitor you throughout the first infusions so that any allergic reaction can be detected and treated immediately.

You, your parent or caregiver must be trained by your doctor before you can infuse Xembify®.

Xembify® is for subcutaneous infusion only. Infuse Xembify® into subcutaneous tissue at sites such as

- abdomen,
- thighs,
- upper arms, and
- the side of the hip

For the initial infusions, do not exceed 25 ml per hour for each infusion site. After 2 infusion sessions, you may be allowed to gradually increase the dose rate to up to 35 ml per hour for each infusion site. Talk to your doctor before increasing the infusion rate.

You may infuse at more than one site at a time, as long as they are at least 5 cm apart. In infants and children infusion sites may be changed every 5 to 15 ml. Adult patients can split the dose between multiple sites, especially if the volume is greater than 30 ml. There is no limit to the number of sites you may use. You may use more than one pump to do this.

When selecting infusion sites, avoid: bony areas, visible blood vessels, scars and any areas of inflammation (irritation) or infection.

Follow the steps below and use aseptic techniques to prepare and infuse Xembify®.

Do not use if tape over carton ends is broken.

Prior to use, allow the solution to come to room temperature (20-25°C). This can take 60 minutes or longer.

Do not apply heat or place in the microwave.

Step 1: Assemble supplies

- Gather the Xembify® vial(s), ancillary supplies, sharps container, patient’s treatment diary/logbook, and the infusion pump(s).

Step 2: Clean surface

- Set up your infusion area on a clean, flat, non-porous surface, such as a kitchen counter. Avoid using porous surfaces such as wood. Clean the surface with an alcohol wipe using a circular motion from the center outward.

Step 3: Wash hands

- Wash and dry your hands thoroughly before using Xembify®. Your healthcare provider may recommend that you use antibacterial soap or that



you wear gloves.

Step 4: Check vials

- The liquid in the vial should be clear to slightly opalescent, and colourless or pale yellow or light brown.

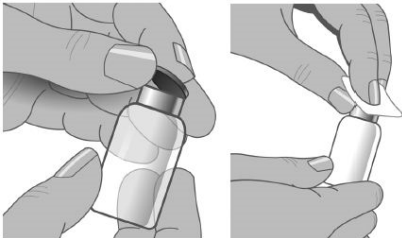
Do not use the vial if:

- the solution is cloudy or discoloured. The solution should be clear to slightly opalescent, and colourless or pale yellow or light brown.
- the protective cap is missing, or if band around vial neck is damaged or missing. Tell your healthcare provider immediately.
- the expiration date has passed.

Step 5: Remove the protective cap

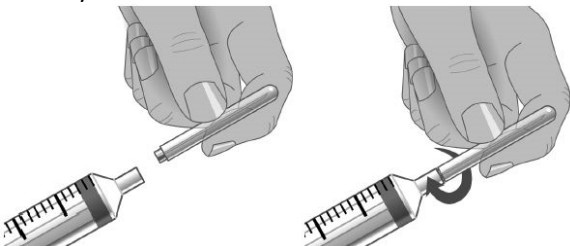
Remove the protective cap from the vial to expose the middle of the stopper.

Wipe the stopper with alcohol and allow to dry.



Step 6: Transfer Xembify® from vial(s) to syringe

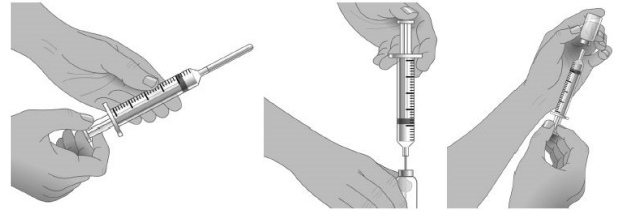
Do not allow your fingers or other objects to touch the inner stem of the plunger, the syringe tip, or other areas that can touch the Xembify® solution. Make sure needles are capped until used and that needles and syringes stay on the clean area created in Step 2. This is called “aseptic technique” to prevent germs from getting into the Xembify®.



Step 7: Prepare the syringe and draw Xembify® solution into syringe

- Remove cap from needle.
- Pull the syringe plunger back to the level matching the amount of Xembify® to be withdrawn from the vial.

- Place the Xembify® vial on a clean flat surface and insert the needle into the center of the vial stopper. Inject air into the vial. The amount of air should match the amount of Xembify® to be withdrawn.
- Turn the vial upside down and withdraw the correct amount of Xembify®. If multiple vials are required to get the correct dose, repeat Step 4

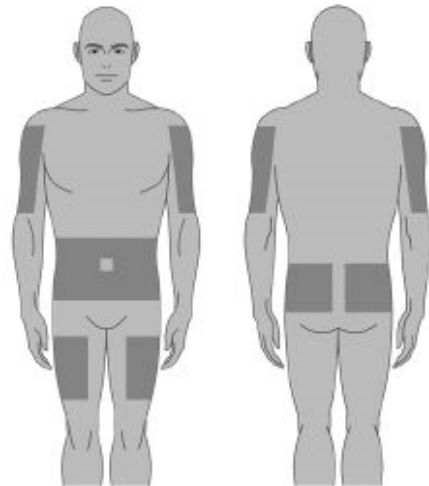


Step 8: Prepare the infusion pump

- Follow the pump manufacturer’s instructions for preparing the infusion pump, administration tubing and Y-site connection tubing, if needed.
- Prime the administration tubing with Xembify® to take out any air left in the tubing or needle. To prime, hold the syringe in one hand and the administration tubing’s capped needle in the other. Gently squeeze on the plunger until you see a drop of Xembify® come out of the needle.

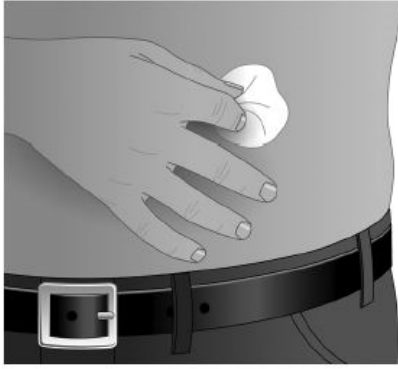
Step 9: Select the number and location of infusion sites

- Select one or more infusion sites as directed by your healthcare provider.
- The number and location of infusion sites depends on the volume of the total dose.
- Avoid: bony areas, visible blood vessels, scars, and any areas of inflammation (irritation) or infection.
- Rotate sites between future infusions.



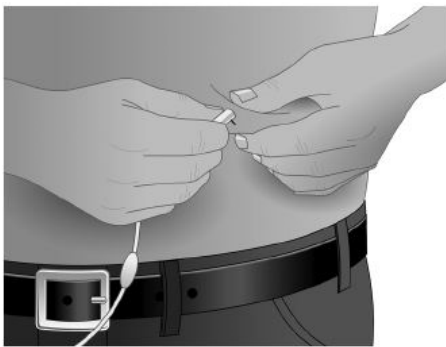
Step 10: Prepare the infusion site

- Wipe the infusion site(s) with a sterile alcohol wipe beginning at the center of each infusion site and moving outward in circular motion. Allow the infusion site(s) to dry (at least 30 seconds).
- Before infusion, sites should be clean, dry, and at least 5 cm apart.



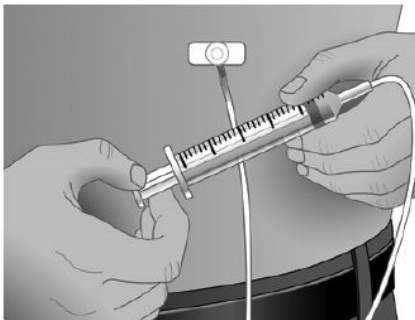
Step 11: Insert the needle

- Grasp the skin between two fingers (pinch at least 2.5 cm of skin) and insert the needle at a 90-degree angle into the tissue underneath the skin or subcutaneous tissue.

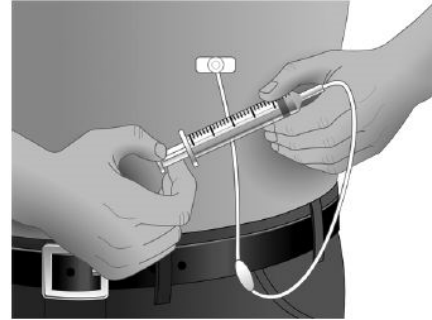


Step 12: Make sure the needle is not in a blood vessel

- After inserting the needle into tissue (and before your infusion), make sure that a blood vessel has not been accidentally entered. To do this, attach a sterile syringe to the end of the primed administration tubing. Pull back on the syringe plunger and watch for any blood flowing back into administration tubing.
- If you see any blood, remove and discard the needle and administration tubing.



- Repeat priming and needle insertion steps using a new needle, administration tubing and a new infusion site.
- Secure the needle in place by applying sterile gauze or transparent dressing over the site



Step 13: Repeat for other sites

Step 14: Infuse Xembify®

- Infuse Xembify® as soon as possible after it is prepared.
- Follow the manufacturer’s instructions for filling the tubing and using the infusion pump.

Step 15: After infusion

- Follow manufacturer’s instructions to turn off the pump.
- Undo and discard any dressing or tape.
- Gently remove the inserted needle(s) or catheter(s).
- Discard any unused solution in an appropriate waste container as instructed.
- Discard any used administration equipment in an appropriate waste container.
- Store your supplies in a safe place.
- Follow manufacturer’s instructions to care for the syringe pump.

Step 16: Record each infusion

- Remove the peel-off label with the product lot number from the Xembify® vial and use this to complete the patient record. Include information about each infusion such as:
 - the time and date,
 - the dose,
 - lot number(s),
 - infusion sites, and
 - any reactions.
- Remember to bring your journal with you when you visit your doctor. Your doctor may ask to see your treatment diary/logbook.
- Tell your doctor about any problems you have during your infusions. Call your healthcare provider for medical advice about side effects.

If you forget to use Xembify®

Xembify® should be used regularly at the intervals determined by your doctor. If you miss your dose at the usual time, do not take a double dose to make up for a forgotten dose. Contact your doctor for instructions.

If you use too much Xembify®

Consequences of an overdose are not known. If you think that you have used too much Xembify®, 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 Xembify®?

Things you should do

Xembify® should be injected just under the skin (subcutaneous). If Xembify® is accidentally given into a blood vessel you could develop shock.

Call your doctor straight away if you:

- feel light headed, dizzy or faint; experience skin rash and itchiness, swelling in the mouth or throat, difficulty breathing, wheezing; experience abnormal heart rate, chest pain, blueness of lips or fingers and toes; or blurred vision. You may be having an allergic reaction.
- experience shortness of breath; chest pains; pain and swelling of an arm or leg; or weakness or numbness on one side of your body. You may have a blood clot in a blood vessel.
- experience severe headache, neck stiffness, drowsiness, fever, extreme sensitivity to light, nausea or vomiting. These side effects may come on hours or even within a few of days after infusing Xembify®. You may have aseptic meningitis syndrome.
- get any side effects, including any possible side effects not listed in this document.

Remind any doctor, dentist or pharmacist you visit that you are using Xembify®.

Things you should not do

- Do not stop using this medicine suddenly.
- Do not use Xembify® after the expiry date which is stated on the label and carton.
- Do not use if the tape at each end of the carton is broken.
- Do not use this medicine if you notice it is cloudy, discoloured, or turbid, or if it has been frozen.
- Do not use if the band around vial neck is broken or missing.

Driving or using machines

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

Xembify® may cause dizziness in some people. If you experience adverse reactions during treatment, you

should wait for these to resolve before driving or operating machines.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Store in a refrigerator (2°C to 8°C).
 - Additionally, Xembify® may be stored at room temperatures (not to exceed 25°C) for up to 6 months any time prior to the expiration date.
 - Any time after room temperature storage, use the product immediately or discard. Do not return to the refrigerator.
- Do not freeze.
- Keep the vial in the outer carton in order to protect from light.

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

Keep it where young children cannot reach it.

When to discard your medicine (as relevant)

Discard Xembify® after:

- the expiration date has passed.
- 6 months of room temperature storage.
- 8 hours has passed once transferred from the vial into a syringe.

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 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
<p>Local reactions at infusion sites:</p> <ul style="list-style-type: none">• Swelling, soreness, redness, induration, local heat, itching, bruising, rash <p>General Disorders:</p> <ul style="list-style-type: none">• chills, headache, dizziness, fever, vomiting, nausea (feeling sick), joint pain, moderate low back pain.	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Immune system disorders including anaphylactic shock, allergic reactions, sudden fall in blood pressure:</p> <ul style="list-style-type: none">• feeling light headed, dizzy or faint• skin rash and itchiness• swelling in the mouth or throat• difficulty breathing, wheezing• abnormal heart rate• chest pain• blueness of lips or fingers and toes• blurred vision <p>Blood clots in a blood vessel:</p> <ul style="list-style-type: none">• chest pain• shortness of breath• pain and swelling of an arm or leg• weakness or numbness on one side of your body <p>Severe irritation of the meninges (membranes covering the brain and spinal cord): Symptoms may occur within hours or a few of days</p> <ul style="list-style-type: none">• severe headache• neck stiffness• drowsiness• fever• extreme sensitivity to light• nausea or vomiting	<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>

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 Xembify® contains

Active ingredient (main ingredient)	Normal immunoglobulin
Other ingredients (inactive ingredients)	IgA (not more than 750 micrograms/mL), water for injections, glycine, and polysorbate 80
Potential allergens	Polysorbate 80, IgA

Xembify® is essentially sodium free.

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

Xembify® does not contain any preservatives, so any unused portion should be discarded immediately.

What Xembify® looks like

Xembify® is a 20% solution for subcutaneous injection. The solution is clear to slightly opalescent and colourless or pale yellow or light brown.

Xembify® is packaged in a carton containing a clear glass vial with a stopper, aluminum overseal, plastic top and shrink band that guarantee the intactness of packaging.

Xembify® is supplied in pack sizes of

1 g / 5 mL Aust R 380405

2 g / 10 mL Aust R 355315

4 g / 20 mL Aust R 380404

10 g / 50 mL Aust R 380406

Not all pack sizes may be marketed.

Who distributes Xembify®

Grifols Australia Pty Ltd.

5/80 Fairbank Road,

Clayton South, Victoria 3169

Australia

For Medical/Technical Enquiries

TOLL FREE: 1 800 339 479

This leaflet was prepared in 30 June 2022.

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