

# Xembify<sup>®</sup> (20% (20 g/100 mL))

## ***Human normal immunoglobulin***

Solution for Subcutaneous Injection

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## **What is in this leaflet**

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Please read this leaflet carefully before you start using Xembify.

This leaflet answers some common questions about Xembify. 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 using Xembify against the benefits they expect it will have for you.

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

Keep this leaflet with you. You may need to read it again.

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## **What Xembify is used for**

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Xembify contains the active ingredient human 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.

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## Before you use Xembify

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### ***When you must not use it***

Do not use Xembify if:

- if you are allergic to human 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 the medicine.

### ***Before you start to use it***

Tell 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.
- 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.

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 [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 breastfeeding 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.

### **Special safety warning**

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.

All infections, thought by a physician, to possibly have been transmitted by this medicine should be reported by the physician or other healthcare provider to Healthcare Logistics Telephone +64 9 918 5100.

Your doctor should discuss the risks and benefits of this medicine with you before administering it to you.

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.

### ***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.

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## How to use Xembify

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### ***How much to take***

- 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 it***

- 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***

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.

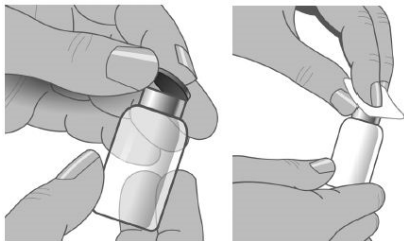
Do not use the vial if:

- 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

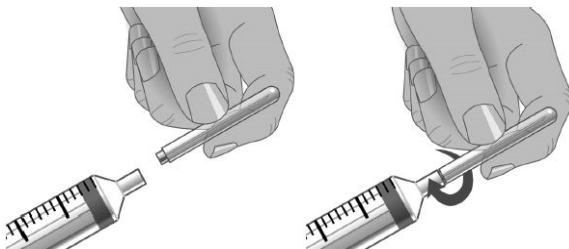
Remove the protective cap from the vial to expose the middle of the stopper.

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.



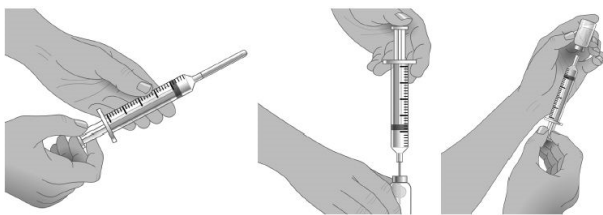
### Step 7: Prepare the syringe and draw Xembify solution into syringe

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.

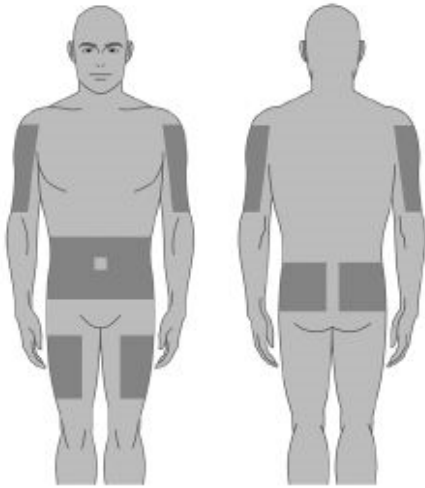
### Step 9: Select the number and location of infusion sites

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.

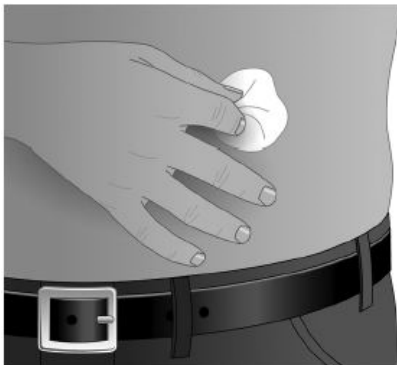
Rotate sites between future infusions.



### Step 10: Prepare the infusion site

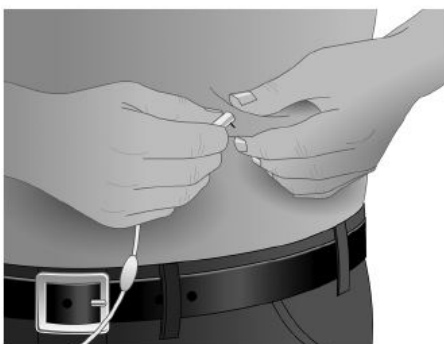
Wipe the infusion site(s) with a sterile alcohol wipe beginning at the center of each infusion site and moving outward in circular motion. Allow the infusion site(s) to dry (at least 30 seconds).

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.

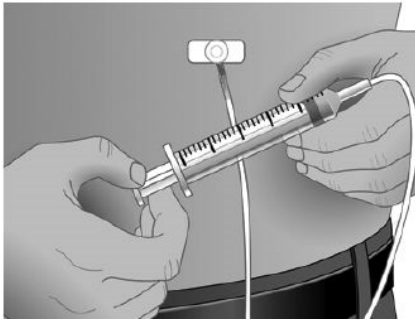




### Step 12: Make sure the needle is not in a blood vessel

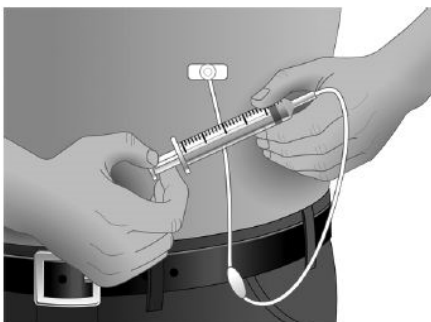
After inserting the needle into tissue (and before your infusion), make sure that a blood vessel has not been accidentally entered. To do this, attach a sterile syringe to the end of the primed administration tubing. Pull back on the syringe plunger and watch for any blood flowing back into administration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

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.

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## **While you are using Xembify**

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### ***Things you must 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 must 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.

### ***Things to be careful of***

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.

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## **In case of overdose**

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### ***If you take too much (overdose)***

Consequences of an overdose are not known. If you think that you have used too much Xembify, you may need urgent medical attention.

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766) or go to accident and emergency at your nearest hospital if you think that you or anyone else may have taken too much Xembify.

Do this even if there are no signs of discomfort or poisoning.

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## Side Effects

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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

<b>Less serious side effects</b>	<b>What to do</b>
<b>Local reactions at infusion sites:</b> Swelling, soreness, redness, induration, local heat, itching, bruising, rash  <b>General Disorders:</b> chills, headache, dizziness, fever, vomiting, nausea (feeling sick), joint pain, moderate low back pain.	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

## Serious side effects

Serious side effects	What to do
<p><b>Immune system disorders including anaphylactic shock, allergic reactions, sudden fall in blood pressure:</b> 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> <p><b>Blood clots in a blood vessel:</b> chest pain shortness of breath pain and swelling of an arm or leg weakness or numbness on one side of your body</p> <p><b>Severe irritation of the meninges (membranes covering the brain and spinal cord):</b> Symptoms may occur within hours or a few of days severe headache neck stiffness drowsiness fever extreme sensitivity to light nausea or vomiting</p>	<p><b>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.</b></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 of side effects

After you have received medical advice for any side effects you experience, you can report side effects to <https://nzphvc.otago.ac.nz/reporting/>. 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.

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## After using Xembify

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### **Storage**

- 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.

### **Disposal**

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.

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.

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## Product description

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

### **What it 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
- 2 g / 10 mL
- 4 g / 20 mL
- 10 g / 50 mL

## ***Ingredients***

### Active ingredient:

- human normal immunoglobulin

### Inactive ingredients:

- glycine
- polysorbate 80
- water for injections

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.

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## **Sponsor Details**

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Xembify is supplied in New Zealand by:

Healthcare Logistics  
58 Richard Pearse,  
Mangere, Auckland, 2022,  
New Zealand

Telephone +64 9 918 5100

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## **Date of Preparation**

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23 May 2024

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