

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 Xeomin?

Xeomin contains the active ingredient incobotulinumtoxinA. Xeomin relaxes the injected muscles or decreases chronic drooping in adults and children aged 2 years to 17 years. For more information, see Section [1. Why am I using Xeomin?](#) in the full CMI.

2. What should I know before I use Xeomin?

Xeomin should only be given by your doctor.

Do not use Xeomin if you:

- Have ever had an allergic reaction to Xeomin or any of the ingredients listed at the end of the CMI.
- Are allergic to any other botulinum toxin.
- Suffer from generalised disorders of muscle activity (e.g., myasthenia gravis, Lambert-Eaton syndrome).
- Have an infection or inflammation at the proposed injection site.

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 Xeomin?](#) In the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Xeomin 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 Xeomin?

Xeomin is a medicine that your doctor will give to you by injection. More instructions can be found in Section [4. How do I use Xeomin?](#) In the full CMI.

5. What should I know while using Xeomin?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, or pharmacist you visit that you are using Xeomin.• If you are going to have surgery, tell the surgeon or anaesthetist that you are using this medicine. It may affect other medicines used during surgery.• If you become pregnant while using this medicine, tell your doctor immediately.• Keep all of your doctor's appointments so that your progress can be checked.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how Xeomin affects you.• Xeomin may cause weakness (asthenia), muscle weakness, vision disorders, dizziness, or drooping eyelids in some people.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Xeomin will be stored by your doctor until it is time for them to give your injection to you.

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

6. Are there any side effects?

The most common side effects are muscle weakness, dry eyes, dry mouth, swallowing difficulties and injection site pain. Serious side effects include difficulty with breathing, swallowing, or speaking, swelling of the face, or swelling of the hands, feet or ankles. 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.

Xeomin[®] (ZEE-oh-min)

Active ingredient(s): *incobotulinumtoxinA*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using Xeomin?

Xeomin contains the active ingredient incobotulinumtoxinA. Xeomin is a peripheral muscle relaxant.

The medicine contains incobotulinumtoxinA, purified neurotoxin free from complexing proteins. This belongs to a family of medicines called peripheral muscle relaxants.

Xeomin is injected into the muscles where it blocks passage of signals from nerves to the muscle. This causes a reduction in the ability of the muscle to contract.

Xeomin is used for the treatment of:

- Cervical dystonia (also known as spasmodic torticollis) in adults, a painful condition that causes involuntary contractions of muscles in the neck causing abnormal head position/twisted neck.
- Blepharospasm in adults, involuntary contractions of muscles in the eyelids.
- Spasticity of the upper limbs in adults and children aged 2 years to 17 years (including shoulders, arms or hands) and of the lower limbs/legs in children aged 2 years to 17 years causing increased muscle tension/uncontrollable muscle stiffness.

Xeomin is also injected into the glands that make saliva and is used to treat sialorrhea (chronic drooling) in adults and children aged 2 years to 17 years.

Xeomin is also injected into facial muscles to improve the look of upper facial lines including frown lines between the eyebrows (glabellar lines), wrinkles at the side of eyes (crow's feet) and horizontal forehead lines in adults.

2. What should I know before I use Xeomin?

Xeomin should only be given by your doctor.

Warnings

Do not use Xeomin if you:

- Are allergic to Xeomin including any of its ingredients listed in Section 7 Product details at the end of this leaflet.
- Are allergic to any other botulinum toxin products
- Suffer from generalised disorders of muscle activity (e.g., myasthenia gravis, Lambert-Eaton Syndrome).
- Have an infection or inflammation at the proposed injection site.

Check with your doctor if you:

- Have allergies to any other medicines, foods, preservatives, or dyes
- Have any other medical conditions
- Take any medicines for any other condition

Tell your doctor if you have any of the following medical conditions:

- Any type of bleeding disorders,
- Treatment with substances that prevent the blood from clotting (anticoagulant therapy),
- Difficulty in swallowing,
- Difficulty in breathing,
- Seizures
- Pronounced muscle weakness or decreased muscle volume in the muscle where you will receive the injection,
- Any other muscle disorders (e.g., amyotrophic lateral sclerosis (ALS), peripheral neuromuscular dysfunction, myasthenia gravis, Lambert-Eaton Syndrome),
- Any disorders of the eye (e.g., glaucoma), especially if you are being treated for blepharospasm,
- Kidney, liver, or heart problems.

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

There is not adequate information available from use in pregnant women. Check with your doctor if you are pregnant or intend to become pregnant.

It is not known if Xeomin is excreted into the breast milk. Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor can discuss the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you are given this medicine.

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.

Xeomin may interact with other medicines that cause muscle relaxation, or which may interfere with breathing.

Tell your doctor if you are taking any other medicines, especially if you:

- have recently received an antibiotic by injection,
- take muscle relaxants,
- take an allergy or cold medicine,
- take a sleep medicine,
- take a blood thinner medicine.

These medicines may be affected by Xeomin or affect how well it works. You may need different amounts of your medicine, or you may need to use a different medicine.

Your doctor has more information on medicines to be careful with or avoid while using this medicine.

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

4. How do I use Xeomin?

Only your doctor will prepare and give you this medicine by injection.

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

How it is given

Xeomin comes as a powder which your healthcare professional will make into a suspension that will then be injected into one or more muscles.

How much to use

- Your doctor will determine the correct dosage to use, depending on your medical condition.

How long to use it

- Your doctor will tell you how often you will require treatment with this medicine.

If you forget your appointment to receive Xeomin

Nothing will happen if you miss a scheduled appointment for your injection other than some of your symptoms may return. Consult your doctor and they will decide when you need your next injection.

If you are given too much Xeomin

This medicine will be given to you under medical supervision. Therefore, it is unlikely that you will be given too much. If you see more than one doctor, be sure to tell them that you are receiving Xeomin.

Symptoms of overdose are not apparent immediately after the injection and may include general weakness, drooping eyelid, double vision, breathing difficulties, speech difficulties, and paralysis of the respiratory muscles or swallowing difficulties which may result in pneumonia.

If you think that you have been given too much Xeomin, 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 Xeomin?

Things you should do

- If you are about to be started on any new medicine, remind your doctor or pharmacist that you are using this medicine.
- Tell any other doctors, dentists and pharmacists who treat you that you are using this medicine.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are using this medicine. It may affect other medicines used during surgery.
- If you become pregnant while using this medicine, tell your doctor immediately.
- Keep all of your doctor's appointments so that your progress can be checked.

Driving or using machines

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

Xeomin may cause weakness (asthenia), muscle weakness, vision disorders, dizziness, or drooping eyelids in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

Xeomin will be stored by your doctor until it is time for them to give your injection to you.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using this medicine.

This medicine helps most people with conditions that involve overactive muscles (e.g., cervical dystonia, blepharospasm, limb spasticity, or upper facial lines), or

chronic drooling/salivation (e.g., sialorrhea) but it may have unwanted side effects in a few people.

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.

The potential for some side effects may increase or decrease depending on the condition you are receiving Xeomin treatment for.

Side effects may occur from misplaced injections of Xeomin temporarily paralysing nearby muscle groups. There have been very rare reports of side effects that may be related to the spread of toxin away from the injection site to produce symptoms like the product effects (e.g., excessive muscle weakness, swallowing difficulties or accidental swallowing of food or drink into the airways). Patients who receive the recommended doses may experience excessive muscle weakness.

If the dose is too high or the injections too frequent, the risk of antibody formation may increase. Antibody formation can cause treatment with Xeomin to fail.

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>These side effects may occur as a result of having Xeomin:</p> <ul style="list-style-type: none"> • drooping eyelids, • dry eyes, • headache, • dry mouth, • nausea, • injection site pain, • rash, • flu-like symptoms, • unusual weakness, • neck pain, • muscular weakness, • musculoskeletal pain, • musculoskeletal stiffness, • muscle spasms, • feeling faint, • upper respiratory tract infection, • increased sweating, • weakness of facial muscles, • tiredness, • blurred vision, visual impairment and double vision, • increased tears, • dizziness, • muscle disorders (raised eyebrows) • swelling of eyelids, • redness, bruising and discomfort (heavy feeling) at the injection site, 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> • heavy feeling of eyelid/eyebrow/forehead, • drooping eyebrow, • brow asymmetry, • facial asymmetry. <p>These side effects may occur as a result of having an injection:</p> <ul style="list-style-type: none"> • pain, swelling or infection at the injection site, • tingling or numbness of the hands or feet, • decreased feeling or sensitivity, especially in the skin, • tenderness, • swelling on any other part of the body, • redness or bruising of the skin, • bleeding, • itching, • low blood pressure (e.g. dizziness, light-headedness), • anxiety, • nausea, • ringing or other persistent noise in the ears, • fainting. 	

Serious side effects

Serious side effects	What to do
<p>These side effects may occur as a result of having Xeomin:</p> <ul style="list-style-type: none"> • difficulty in swallowing, • difficulty in speaking, • difficulty in breathing, • breathlessness, • exaggerated muscle weakness, • immediate allergic reaction (e.g., shortness of breath, wheezing or difficulty in breathing, swelling of the hands, feet, ankles, face, lips, mouth, throat or other parts of the body, rash, itching or hives on the skin) 	<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. Serious side effects that may affect 1 in 10 people or more for specific treatments are listed below.

Treatment for cervical dystonia (spasmodic torticollis)

After the injection you may develop mild to severe swallowing difficulties. This may lead to problems with breathing, and you may have a higher risk of accidental swallowing of food or drink into the airways. Foreign substances in your lungs may lead to an inflammation or

infection (pneumonia). Your doctor will give you special medical treatment if needed (e.g., in the form of artificial nutrition).

Swallowing difficulties can last for up to two to three weeks after injection, for one patient a duration of up to five months is known.

If you have been inactive for a long period of time, any activity should be started gradually after treatment with Xeomin.

Treatment for blepharospasm (involuntary eyelid movement)

People who receive Xeomin to treat eyelid spasm may experience drooping or paralysis of the upper eyelid. This may result in reduced blinking, which can lead to a prolonged exposure of the transparent front part of the eye (cornea). This exposure may lead to a damaging of the surface and an inflammation (corneal ulceration) or other problems of the cornea. Contact your doctor if you have eye pain or irritation after treatment with Xeomin.

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 Xeomin contains

Active ingredient (main ingredient)	IncobotulinumtoxinA
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• Sucrose• Albumin (human)

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

This medicine does not contain lactose, gluten, tartrazine, or any other azo dyes.

What Xeomin looks like

Xeomin intramuscular injection is a freeze-dried white to off-white powder contained in a glass bottle closed with a rubber stopper and sealed with an aluminium cap.

Xeomin is available in vials containing 50 or 100 units.

Australian Registration Numbers

AUST R 205507: Xeomin 50-unit vial

AUST R 205508: Xeomin 100-unit vial.

Who distributes Xeomin

Xeomin is supplied in Australia by:

Merz Australia Pty Ltd
Suite 8.01A, 189 O'Riordan Street
Mascot NSW 2020

Xeomin is supplied in New Zealand by:

Healthcare Logistics
58 Richard Pearse Drive
Mangere
Auckland 2022
New Zealand

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