

Xeomin®

(ZEE-oh-min)

incobotulinumtoxinA

Purified Botulinum toxin type A free from complexing proteins

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Xeomin.

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 this medicine 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.

You may need to read it again.

What Xeomin is used for

The medicine is used:

- To treat the abnormal head position and neck pain that happens with cervical dystonia in adults,
- To treat abnormal spasm of the eyelids (blepharospasm) in adults,
- Spasticity of the upper limbs in adults,
- 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.

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.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

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

Xeomin has only been examined for safety and effectiveness in adults. It is not recommended for use in children.

Before you are given Xeomin

When you must not use it

Do not use the medicine if you have an allergy to:

- any medicine containing incobotulinumtoxinA,
- any of the ingredients listed at the end of this leaflet.

Do not use the medicine if you have an:

- existing generalised disorder of muscle activity (e.g. myasthenia gravis, Lambert-Eaton Syndrome),

- infection or inflammation at the proposed injection site.

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

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

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had 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.

Tell your doctor if you are pregnant or plan to become pregnant.

Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are breastfeeding.

Your doctor can discuss with you 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.

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.

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 may 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.

How to use Xeomin

Only your doctor will prepare and administer this medicine.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

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 are given too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26) if you think you may have been given too much Xeomin. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include:

- general weakness,
- drooping of the upper eyelid,
- double vision,
- difficulty in breathing,
- difficulty in speaking,
- difficulty in swallowing.

Discuss any worries you may have about this with your doctor.

While you are using Xeomin

Things you must 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.

Things to be careful of

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

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

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, upper limb spasticity, or glabellar frown lines), but it may have unwanted side effects in a few people. All medicines can have side effects, sometimes they are serious, most of the time they are not. You may need medical attention if you experience some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor to answer any questions you may have.

Some side effects can occur as a result of having an injection. Tell your doctor if you experience any of the following:

- 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, lightheadedness),
- anxiety,
- nausea,
- ringing or other persistent noise in the ears,
- fainting.

Tell your doctor if you notice any of the following and they worry you:

- difficulty in swallowing,
- drooping eyelids,
- dry eyes,
- headache,
- dry mouth,
- nausea,
- injection site pain,
- 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,
- facial asymmetry.

The above list includes the more common side effects of your medicine.

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

- difficulty in swallowing,
- difficulty in speaking,
- difficulty in breathing,
- 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).

The above list includes side effects that may be serious or life-threatening and may therefore require immediate medical attention. Serious side effects are rare.

Other side effects have also occurred in some patients. Tell your doctor if you experience any of the following:

- rash,
- flu-like symptoms,
- heavy feeling of eyelid/eyebrow/forehead,
- drooping eyebrow
- brow asymmetry,
- breathlessness.

Tell your doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Product description

What it 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.

Ingredients

Xeomin contains incobotulinumtoxinA as the active ingredient.

Xeomin also contains the following inactive ingredients:

- sucrose,
- albumin (human).

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

Sponsor

Xeomin is supplied in Australia by:

Merz Australia Pty Ltd
Level 3, 244 Coward Street
Mascot NSW 2020

Xeomin is supplied in New Zealand by:

Healthcare Logistics
58 Richard Pearse Drive
Mangere
Auckland 2022
New Zealand

Australian Registration Number

AUST R 205507: 50 unit vial

AUST R 205508: 100 unit vial

This leaflet was prepared in Feb 2019.