

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrBOTOX COSMETIC®

onabotulinumtoxinA

Read this carefully before you start taking Botox Cosmetic and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about Botox Cosmetic.

Serious Warnings and Precautions

- The term “Allergan unit” upon which dosing is based is a specific measurement of toxin activity that is unique to AbbVie’s formulation of Botox and Botox Cosmetic. Therefore, the “Allergan units” used to describe Botox and Botox Cosmetic's activity are different from those used to describe that of other botulinum toxin preparations and the units representing Botox and Botox Cosmetic’s activity are NOT interchangeable with other products.
- Botox Cosmetic should only be given by a physician or authorized prescriber with the appropriate qualifications and experience in the treatment and the use of required equipment.
- The recommended dosage and frequency of administration for Botox should be followed.
- DISTANT SPREAD OF TOXIN EFFECT: The effects of Botox Cosmetic and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life-threatening and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity, but symptoms can occur in adults, particularly in those patients who have underlying conditions that would predispose them to these symptoms.

What is Botox Cosmetic used for?

- Botox Cosmetic is used to treat upper facial lines, including forehead, crow’s feet, and frown lines.

How does Botox Cosmetic work?

Botox Cosmetic is a muscle relaxant. When injected into muscles, it blocks part of the nerve signals (impulses) to those muscles. It also reduces the movement of those muscles. This causes muscle relaxation, which goes away over time.

What are the ingredients in Botox Cosmetic?

Medicinal ingredient: OnabotulinumtoxinA

Non-medicinal ingredients: Albumin (human) and sodium chloride.

Botox Cosmetic comes in the following dosage forms:

Sterile vacuum-dried concentrate; powder for solution for injection; 50 and 100 Allergan units per vial.

Do not use Botox Cosmetic if:

- you are allergic or sensitive to any of the ingredients.
- you have an infection in the muscles where Botox Cosmetic is injected.
- you have any muscle disorders, such as myasthenia gravis, Eaton Lambert Syndrome or amyotrophic lateral sclerosis.

To help avoid side effects and ensure proper use, talk to your doctor or healthcare professional before you take Botox Cosmetic. Talk about any health conditions or problems you may have, including if you:

- have myasthenia gravis or Eaton Lambert Syndrome, amyotrophic lateral sclerosis or another muscle disorder.
- are allergic or sensitive to Botox Cosmetic.
- have an infection at a proposed injection site.
- are scheduled to have surgery using a general anaesthetic (a medicine that reduces your sensitivity to pain).
- are taking or are likely to take antibiotics, especially aminoglycoside antibiotics.
- are pregnant or become pregnant while taking this drug. Botox Cosmetic given to pregnant rabbits caused abortion or birth defects.
- are nursing. We don't know yet if this drug gets into human milk and can be passed to your baby.

Botox Cosmetic is for intramuscular use only.

Other warnings you should know about:

Seek immediate medical care if swallowing, speech or respiratory problems arise.

Tell your healthcare professional if you experience any difficulties in swallowing food while on Botox Cosmetic, as it could be related to the dosage. Difficulty in swallowing food, ranging from very mild to severe, can persist for 2-3 weeks after injection, or longer.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Botox Cosmetic:

The effect of Botox Cosmetic may be increased by aminoglycoside antibiotics (e.g., streptomycin, tobramycin, neomycin, gentamicin, netilmicin, kanamycin, amikacin), spectinomycin, polymyxins, tetracyclines, lincomycin or any other drugs that interfere with neuromuscular transmission.

How to take Botox Cosmetic:

Botox Cosmetic will be given to you by a healthcare professional in a healthcare setting.

- Intramuscular Use

Usual dose:

Botox Cosmetic is injected into your muscles (intramuscularly). It is injected directly into the affected area of your body. Your healthcare professional will usually inject Botox Cosmetic into several sites within each affected area.

A unit of Botox Cosmetic is a dose measurement that is specific to Botox Cosmetic and cannot be interchanged with the units used to measure other botulinum toxin products.

The amount in your injection and how long the effect will last depends on the reason you are taking Botox Cosmetic (forehead, crow’s feet, frown lines, or combination of the three). Therefore, your healthcare professional will decide how much, how often, and in which muscle(s) Botox Cosmetic will be given to you. Your healthcare professional should use the lowest effective dose that works for your condition. Your dose can be increased in subsequent treatments if needed.

The effects last about 3 months. After 3 months, you can receive another treatment.

If you feel that the effect of Botox Cosmetic is not optimal, let your healthcare professional know. There are several potential reasons for this that your healthcare professional can assess.

Overdose:

If you think you, or a person you are caring for, have taken too much Botox Cosmetic, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using Botox Cosmetic?

These are not all the possible side effects you may feel when taking Botox Cosmetic. If you experience any side effects not listed here, contact your healthcare professional.

General

Pain, tenderness and/or bruising at the site of injection. Malaise (generally feeling unwell), lasting up to six weeks after injection with Botox Cosmetic. Weakness and rarely, changes in the way the heart beats, chest pain, skin rash and allergic reaction (symptoms: shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin).

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
RARE			
Difficulty Swallowing		✓	
Difficulty Breathing		✓	

The following side effects were reported in clinical trials: headache, drooping eyelid, eyelid swelling, eyelid change, bruising under the skin, aching or itching forehead, double vision, asymmetric smile, skin tightness (including raising of the outer eyebrows), face pain, injection site pain/burning/stinging, swelling of the injection site, nausea, local muscle weakness, redness of the skin and abnormal sensation.

The following events have been reported rarely (<0.1%) since Botox Cosmetic has been marketed: skin rash, itching, allergic reaction (including anaphylaxis), dysphagia, respiratory compromise, seizures, facial paralysis, dry mouth, abdominal pain, anorexia, diarrhea, vomiting, eye problems including glaucoma, double vision, blurred vision decreased eyesight, dry eye, ear problems including not hearing well, tinnitus, numbness in your face, localised muscle twitches, tiredness. There have also been rare reports after botulinum toxin treatment of adverse events involving the cardiovascular system, including arrhythmia and myocardial infarction, some with fatal outcomes. Some of these patients had risk factors, including cardiovascular disease.

Eyelid swelling has been reported following injections into area around eyes.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store the vacuum-dried product either in a refrigerator at 2 - 8°C, or in a freezer at or below -5° C.

Keep out of reach and sight of children.

If you want more information about Botox Cosmetic:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>); the manufacturer's website www.abbvie.ca or by calling 1-888-704-8271.

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