

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PR BOEY®

TrenibotulinumtoxinE for Injection

This Patient Medication Information is written for the person who will be taking **Boey**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **Boey**, talk to a healthcare professional.

Serious warnings and precautions box

- **Distant spread of toxin effects.** It is possible that the effect of botulinum toxin may affect areas of the body away from the injection site and cause symptoms of a serious condition called botulism. Trouble breathing and trouble swallowing can be life threatening.
- One unit (amount) of Boey is NOT the same as one unit of other botulinum products.
- Boey should only be given by a trained healthcare professional. They should have experience using Boey.
- Follow the dose and schedule of injection recommended by your healthcare provider.

What Boey is used for:

Boey is used in adults to temporarily improve the appearance of moderate to severe frown lines between the eyebrows (glabellar/frown lines).

How Boey works:

Boey is injected into muscles between the eyebrows. It works by blocking the signals that tell the muscles to move. This can reduce the appearance of wrinkles or lines where Boey is injected.

Boey begins working early once it is injected. This effect lasts for a short period of time.

The ingredients in Boey are:

Medicinal ingredient(s): TrenibotulinumtoxinE

Non-medicinal ingredients: L-Histidine, L-Histidine Hydrochloride Monohydrate, L-Methionine, Poloxamer 188, Sodium Chloride, Trehalose Dihydrate

Boey comes in the following dosage form(s):

Powder for solution for injection in a single-use vial; 1400 U / vial

Do not use Boey if:

- If you are allergic to botulinum toxin or any of the other ingredients (listed in “The ingredients in Boey are:”)
- If you have a skin infection where you plan to get the injection

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

- You have allergies to any botulinum toxin product
- You had a side effect from any botulinum toxin product in the past
- You have had facial surgery or injured your face
- You are planning to have facial surgery soon
- You have any redness or swelling (inflammation) where you plan to get an injection
- Your muscles where the injection will be given are weak
- You have drooping of one or both eyelids (ptosis)
- You have any other change in the way your face normally looks
- You have certain diseases that affect your nervous system (such as amyotrophic lateral sclerosis or motor neuropathy)

Other warnings you should know about:

- **Injection site reactions:** Like with any injection procedure, injection site reactions may happen after receiving Boey. Symptoms at the injection site(s) may include:
 - Pain/discomfort
 - Swelling/inflammation
 - Redness
 - Bruising
 - Bleeding
 - Itching
 - Warmth
 - Hardness at the site where the needle entered your skin
- **Muscle weakness in areas next to or near the injection sites:** such as eyelid drooping and double vision (seeing two objects when there is only one).

Driving and using machines: If you have drooping eyelids or problems with your vision after using Boey, do not drive or use machinery until those symptoms go away.

After you get Boey, talk to your healthcare professional if you have the following:

- **Allergic reaction:** An allergic reaction is a reaction your body has to a medicine. This can cause symptoms such as hives, rash, or fever. Contact your healthcare professional right away if you have any of the symptoms listed below as they can be signs of a severe allergic reaction:
 - Trouble breathing, swallowing, or speaking
 - Swelling, including swelling of the face or throat
 - Wheezing (a whistling sound while breathing)
 - Feeling dizzy or light-headed

- Shortness of breath
- **Distant spread of toxin effect:** Sometimes, the effects of botulinum toxin may spread from the injection area to other parts of the body. Contact your healthcare provider right away if you have any of the symptoms listed below:
 - Muscle weakness
 - Trouble swallowing
 - Unwanted food or liquid going into the airways
- **Reduced blinking or experience dryness** in one or both eyes.

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 Boey:

- A different medicine that has botulinum toxin
- Muscle relaxants (medicines that reduce muscle tension)
- Antibiotics (medicines used to treat infections)
- Anticholinergics (medicines that reduce muscle strength)

Ask your healthcare provider for advice before you take any new medicines.

How to take Boey:

Boey should only be given by healthcare professionals with the right training and experience in the treatment of patients.

Boey is injected directly into the muscles (intramuscularly) at five injection sites between the eyebrows.

Boey is not recommended for patients younger than 18.

Usual dose:

The usual dose is 700 Units in total. You will be injected with 140 Units of Boey into each of the five injection sites.

Your healthcare professional will tell you when you should get another Boey treatment based on the appearance of your frown lines.

Overdose:

Contact your healthcare professional immediately if you notice symptoms that you might have received too much Boey. These symptoms may not happen for several days after the injection, and include:

- Muscle weakness. This can happen near or away from the injection site.
- Trouble breathing, swallowing, or speaking. This may happen because the muscle cannot move (muscle paralysis).
- Lung infection called aspiration pneumonia. This may be caused by food or liquid accidentally going into your lungs because the muscles cannot move (muscle paralysis).
- Drooping of the eyelids
- Double vision (seeing two objects when there is only one)

- Overall weakness in the body

If you swallow Boey or have it accidentally injected, see your healthcare provider. They may want to watch you closely for several days.

If you think you, or a person you are caring for, have taken too much Boey, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Possible side effects from using Boey:

Boey can have side effects, although not everybody gets them.

Side effects may include:

Uncommon: These may happen in up to 1 in 100 patients.

- Drooping eyelid
- Drooping eyebrow

Rare: These may happen in up to 1 in 1000 patients.

- Raising of the outer eyebrow

These are not all the possible side effects you may have when taking Boey. If you experience any side effects not listed here, tell your healthcare professional.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell 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 (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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

Storage:

Keep out of reach and sight of children.

Your healthcare provider should not use this medicine after the expiry date.

Your healthcare provider will store this medicine in a refrigerator between 2 to 8°C. Your healthcare professional should keep the vial in the original carton in order to protect from light.

After mixing the powder with salt water, the medicine should be used immediately. It can be stored for up to 24 hours in a refrigerator between 2 to 8°C.

If you want more information about Boey:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website ([Drug Product Database: Access the database](#)); the manufacturer's website www.abbvie.ca; or by calling 1-888-704-8271.

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