

MEDICATION GUIDE
JEUVEAU (pronounced Jū vō)
(prabotulinumtoxinA-xvfs)
for Injection

What is the most important information I should know about JEUVEAU?

JEUVEAU may cause serious side effects that can be life threatening. Call your healthcare provider or get medical help right away if you have any of these problems after treatment with JEUVEAU:

- **Problems swallowing, speaking, or breathing.** These problems can happen hours, days, or weeks after an injection of JEUVEAU if the muscles that you use to breathe and swallow become weak after the injection. Death can happen as a complication if you have severe problems with swallowing or breathing after treatment with JEUVEAU.
 - People with certain breathing problems may need to use muscles in their neck to help them breathe. These people may be at greater risk for serious breathing problems with JEUVEAU.
 - Swallowing problems may last for several months. People who cannot swallow well may need a feeding tube to receive food and water. If swallowing problems are severe, food or liquids may go into your lungs. People who already have swallowing or breathing problems before receiving JEUVEAU have the highest risk of getting these problems.
- **Spread of toxin effects.** In some cases, 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. The symptoms of botulism include:
 - loss of strength and muscle weakness all over the body
 - blurred vision and drooping eyelids
 - trouble saying words clearly
 - trouble breathing
 - double vision
 - hoarseness or change or loss of voice
 - loss of bladder control
 - trouble swallowing

These symptoms can happen hours, days, or weeks after you receive an injection of JEUVEAU.

These problems could make it unsafe for you to drive a car or do other dangerous activities. See **“What should I avoid while receiving JEUVEAU?”**

What is JEUVEAU?

JEUVEAU is a prescription medicine that is injected into muscles and used in adults for a short period of time (temporary) to improve the look of moderate to severe frown lines between the eyebrows (glabellar lines).

It is not known if JEUVEAU is safe and effective for use in children.

Do not receive JEUVEAU if you:

- are allergic to JEUVEAU or any of the ingredients in JEUVEAU. See the end of the Medication Guide for a list of ingredients in JEUVEAU.
- had an allergic reaction to any other botulinum toxin product such as rimabotulinumtoxinB (MYOBLOC), onabotulinumtoxinA (BOTOX, BOTOX COSMETIC), abobotulinumtoxinA (DYSPOUR), or incobotulinumtoxinA (XEOMIN).
- have a skin infection at the planned injection site.

Before receiving JEUVEAU, tell your healthcare provider about all your medical conditions, including if you:

- have a disease that affects your muscles and nerves (such as amyotrophic lateral sclerosis [ALS or Lou Gehrig’s disease], Myasthenia gravis or Lambert-Easton syndrome). See **“What is the most important information I should know about JEUVEAU?”**
- had any side effect from any botulinum toxin product in the past
- have or have had a breathing problem, such as asthma or emphysema
- have or have had swallowing problems
- have or have had bleeding problems
- have or have had heart problems
- have plans to have surgery
- have weakness of your forehead muscles, such as trouble raising your eyebrows
- have drooping eyelids
- have had surgery on your face
- have had dry eye with use of botulinum toxin products in the past

- are pregnant or plan to become pregnant. It is not known if JEUVEAU can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if JEUVEAU passes into breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with JEUVEAU.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements.

Using JEUVEAU with certain other medicines may cause serious side effects. **Do not start any new medicines until you have told your healthcare provider that you have received JEUVEAU in the past.**

Especially tell your healthcare provider if you:

- have received any other botulinum toxin product in the last 4 months
- have received injections of botulinum toxin, such as onabotulinumtoxinA (BOTOX, BOTOX COSMETIC) rimabotulinumtoxinB (MYOBLOC), abobotulinumtoxinA (DYSPOUR) or incobotulinumtoxinA (XEOMIN). Be sure your healthcare provider knows exactly which product you received.

Know the medicines you take. Keep a list of your medicines with you to show your healthcare provider and pharmacist each time you get a new medicine.

How will I receive JEUVEAU?

- JEUVEAU is an injection that your healthcare provider will give you.
- JEUVEAU is injected into your affected muscles.
- JEUVEAU should not be received more than 1 time every 3 months.
- Your healthcare provider may change your dose of JEUVEAU, until you and your healthcare provider find the best dose for you.
- Your healthcare provider will tell you how often you will receive your dose of JEUVEAU injections.

What should I avoid while receiving JEUVEAU?

JEUVEAU may cause loss of strength or general muscle weakness, vision problems, or dizziness within hours to weeks of receiving JEUVEAU. **If this happens, do not drive a car, operate machinery, or do other dangerous activities.** See “**What is the most important information I should know about JEUVEAU?**”

What are the possible side effects of JEUVEAU?

JEUVEAU can cause serious side effects, including:

- See “**What is the most important information I should know about JEUVEAU?**”
- **Allergic reactions.** Symptoms of an allergic reaction to JEUVEAU may include: itching, rash, hives, wheezing, trouble breathing, or you may become dizzy or faint. Tell your healthcare provider or get emergency medical help right away if you develop wheezing or trouble breathing, or if you feel dizzy or faint.
- **Heart problems.** Irregular heart beat and heart attack that have caused death, have happened in some people who received botulinum toxin products.
- **Eye problems.** Dry eye, reduced blinking, and corneal problems have happened in some people who receive JEUVEAU to treat glabellar lines. Tell your healthcare provider if you develop eye pain or irritation, sensitivity to light, or changes in your vision.

The most common side effects of JEUVEAU include:

- headache
- eyelid drooping
- upper respiratory infection
- increased white blood cell count in your blood

These are not all the possible side effect of JEUVEAU.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of JEUVEAU.

Medicines are sometime prescribed for purposes other than those listed in a Medication Guide. You can ask your healthcare provider or pharmacist for information about JEUVEAU that is written for healthcare professionals.

What are the ingredients in JEUVEAU?

Active ingredient: botulinum toxin type A

Inactive ingredients: human serum albumin and sodium chloride

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