Pr NUCEIVA™

prabotulinumtoxinA
injection

Please see Important Safety Information, including serious warnings and precautions on pages 8-9, and accompanying full Prescribing Information.

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Indication
Nuceiva™ is indicated for the temporary improvement in the appearance of moderate to severe frown lines (glabellar lines) in adult patients <65 years of age.

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Hello, Nuceiva™

Now that you have been prescribed Nuceiva by your doctor, here is some important information you should know before your treatment.

Nuceiva™ is indicated for the temporary improvement in the appearance of moderate to severe frown lines (known as glabellar lines) in adult patients <65 years of age. [1]

Do not receive Nuceiva™ if you are allergic or sensitive to any of the ingredients, you have an infection in the muscles where it would be injected, or you have any muscle disorders in other parts of your body. [1]

Please see Important Safety Information on pages 8-9.

What is a Glabellar Line?

Glabellar lines, also known as frown lines, are vertical lines on the forehead, and are moderate to severe when they become visible. Glabellar lines form as the corrugator and/or procerus muscles in the face are active.[2]

Nuceiva™ can only be used by health care professionals experienced in the injection of botulinum toxin.

Dosage: The optimum dosage and number of injection sites in the treated muscle will be chosen by your doctor. [1]

A NEW NEUROMUSCULAR BLOCKING AGENT

Please see Important Safety Information on pages 8-9.

BEFORE

AFTER (DAY 30)

Nuceiva™ patient at maximum frown.

Unaltered results with no complementary products

Depicts typical results-Individual results may vary

How does Nuceiva™ work?

Nuceiva™ is a drug that temporarily reduces movement of muscles that cause wrinkles. Some patients see results as soon as two days after injection. [1]

Please see Important Safety Information on pages 8-9.

UNRETOUCHED RESULTS

Please see Important Safety Information on pages 8-9.

BEFORE

AFTER (DAY 30)

Nuceiva™ patient at maximum frown.

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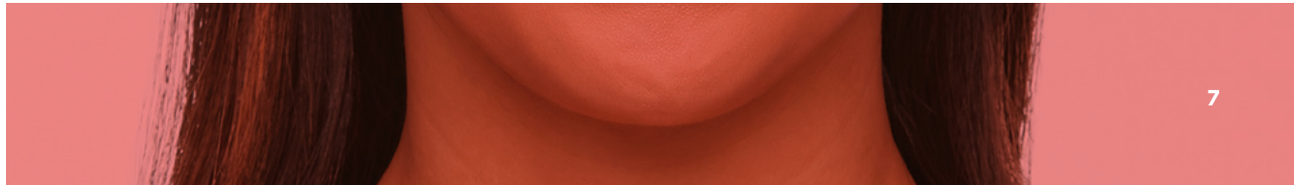

IMPORTANT SAFETY INFORMATION FOR NUCEIVA™ (prabotulinumtoxinA)
READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE PATIENT MEDICATION INFORMATION

Read this carefully before you start taking NUCEIVA and each time you are re-treated. 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 NUCEIVA.

Serious Warnings and Precautions

• Side effects may occur from misplaced injections of NUCEIVA temporarily paralyzing nearby muscle groups. There have been very rare reports of side effects that may be related to the spread of Botulinum neurotoxin distant from the injection site. These may include excessive muscle weakness, swallowing and breathing difficulties, or accidental swallowing of food or drink into the airway, which can be life threatening or fatal. These symptoms have been reported hours to weeks after injection. Patients who receive the recommended doses may very rarely experience excessive muscle weakness.

What are the ingredients in NUCEIVA
Medicinal ingredients: Botulinum toxin Type A
Non-medicinal ingredients: Human serum albumin and sodium chloride

NUCEIVA comes in the following dosage forms: a single-use, sterile vial (100 Units).

Do not use NUCVEIVA if:
- you are allergic or sensitive to any of the ingredients
- you have an infection in the muscles where it would normally be injected
- you have any muscle disorders in other parts of your body, such as myasthenia gravis, Eaton Lambert Syndrome or amyotrophic lateral sclerosis

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take NUCEIVA. Talk about any health conditions or problems you may have including if:
- you have muscle disorders
- have received any other botulinum toxin product in the last four months
- you have eye disorders including drooping eyes, dry eyes
- have bleeding problems
- you have pre-existing swallowing or breathing difficulties
- you are allergic or sensitive to any botulinum toxin product
- you have an infection at the proposed injection site
- you are scheduled to have surgery using a general anesthetic
- you are taking or are likely to take antibiotics, especially aminoglycoside antibiotics
- you are pregnant or become pregnant while taking this drug
- you are nursing. It is not known whether this drug is excreted in human milk

NUCEIVA is for intramuscular use only.

NUCEIVA should only be injected by a physician with the appropriate qualifications and experience in the treatment and use of botulinum toxin products.

NUCEIVA may cause loss of strength or general muscle weakness, blurred vision, or drooping eyelids within hours to weeks after injection. If this happens, do not drive a car, operate machinery, or do other dangerous activities.

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

Tell your doctor if you experience any difficulties in swallowing food after NUCEIVA treatment, as it could be related to the dosage. Difficulty in swallowing food, ranging from very mild to severe, which can persist for 2–3 weeks after injection, or longer has been reported with use of botulinum toxins.

Tell your doctor if you are taking other medicines, including those you have bought at your pharmacy, supermarket or health food shop.

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

How to take NUCEIVA:
NUCEIVA can only be used by health care professionals experienced in the injection of botulinum toxin.

Usual Dose:
The optimum dosage and number of injection sites in the treated muscle will be chosen by your doctor.

Overdose:
Symptoms of overdose for this product, as for all botulinum toxins, are related to the dose, the condition being treated and susceptibility of the patient. Symptoms are not apparent immediately after the injection and may include general weakness, drooping eyelid, double vision, swallowing and speech difficulties, and pneumonia.

In case you feel symptoms of overdose please seek medical emergency services immediately or ask your relatives to do so and seek medical attention urgently. Medical supervision for up to several days and assisted ventilation may be necessary.

If you have any further questions on the use of this product ask your doctor or pharmacist

If you think you have taken too much NUCEIVA, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

What are possible side effects from using Nuceiva?
These are not all the possible side effects you may feel when taking NUCEIVA. If you experience any side effects not listed here, contact your healthcare professional.

The most commonly reported NUCEIVA side effects (≥ 1%) were headache, drooping eyelid or brow, injection site reactions (e.g. pain, brusing, itchy skin, swelling) and upper respiratory infection or sinus infection.

Other potential side effects can include allergic reactions (e.g. eyelid edema, wheezing), blurred vision or double vision, temporary facial paralysis close to injection site, and urinary tract infection.

This is not a complete list of side effects. For any unexpected effects while taking NUCEIVA, contact your doctor or pharmacist.

If you have troublesome symptoms or side effects that are 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 ((http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by tax; or
- Calling toll-free at 1-866-234-2345

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

Storage:
Keep out of the reach and sight of children.
NUCEIVA must be stored under refrigeration at 2-8°C. Once reconstituted, it can be stored under refrigeration at 2-8°C for up to 24 hours. Do not freeze after reconstitution.

If you want more information about NUCEIVA:

- 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

REFERENCES:

1. Product Monograph Nuceiva (Aug 16-2018)
2. Data on file; CSR EV-001, BLA761085. Evolus, Inc., Santa Barbara, CA.

Manufactured by: Evolus, Inc., 1027 Garden St., Santa Barbara, CA 93101
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