

# [NUCEIVA]\*

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details. [Include if applicable]

### 1. Why am I using NUCEIVA?

NUCEIVA contains the active ingredient prabotulinumtoxinA. NUCEIVA is used to temporarily improve the look of moderate to severe frown lines between the eyebrows (glabellar lines) in adults.

For more information, see Section [1. Why am I using NUCEIVA?](#) in the full CMI.

### 2. What should I know before I use NUCEIVA?

Do not use if you have ever had an allergic reaction to prabotulinumtoxinA or any of the ingredients listed at the end of the CMI.

Do not use if you have a skin infection at the planned injection site.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use NUCEIVA?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with NUCEIVA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use NUCEIVA?

- NUCEIVA should only be injected by doctors with appropriate qualifications and expertise in the treatment of frown lines.
- 4 Units of NUCEIVA will be injected into 5 different sites by your doctor, totaling to 20 Units.
- Unit doses for NUCEIVA are not interchangeable with those used for other preparations of botulinum toxin.

More instructions can be found in Section [4. How do I use NUCEIVA?](#) in the full CMI.

### 5. What should I know while using NUCEIVA?

Things you should do	<ul style="list-style-type: none"><li>• Remind any doctor, dentist, or pharmacist you visit that you are using NUCEIVA.</li></ul>
Things you should not do	<ul style="list-style-type: none"><li>• Do not start any new medicines until you have told your doctor that you have received NUCEIVA in the past.</li></ul>
Driving or using machines	<ul style="list-style-type: none"><li>• NUCEIVA may cause muscle weakness, dizziness, and visual disturbance in some people. Do not drive or use machinery until such effects have cleared.</li></ul>
Looking after your medicine	<ul style="list-style-type: none"><li>• Refrigerate; do not freeze</li></ul>

For more information, see Section [5. What should I know while using NUCEIVA?](#) in the full CMI.

### 6. Are there any side effects?

Common but usually mild potential side effects include headache and eyelid drooping.

Serious potential side effects can include problems swallowing, speaking, breathing, or spread of toxin effects including loss of strength and all-over muscle weakness. While rare, these may occur at any time (hours to weeks) and could be life threatening requiring medical attention right away.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

# NUCEIVA<sup>®</sup> (phonetic pronunciation – nu see va)

**Active ingredient(s):** *prabotulinumtoxinA*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using NUCEIVA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using NUCEIVA.**

**Where to find information in this leaflet:**

- [1. Why am I using NUCEIVA?](#)
- [2. What should I know before I use NUCEIVA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use NUCEIVA?](#)
- [5. What should I know while using NUCEIVA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using NUCEIVA?

**NUCEIVA contains the active ingredient prabotulinumtoxinA.** NUCEIVA is a neuromuscular blocking agent that works by blocking the nerve impulses to the muscles in which it has been injected. This prevents the muscles from contracting.

**NUCEIVA is a prescription medicine used to temporarily improve the look of moderate to severe frown lines between the eyebrows (glabellar lines) in adults.**

## 2. What should I know before I use NUCEIVA?

### Warnings

**Do not use NUCEIVA if:**

- you are allergic to prabotulinumtoxinA, or any of the ingredients listed at the end of this leaflet;
- have a skin infection at the planned injection site.

**Check with your doctor 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).
- take any medicines for any other condition.
- had any side effect from any botulinum toxin product in the past.
- have received any other botulinum toxin product in the last 4 months.

- 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.

As this product contains a derivative of human blood, there is an extremely remote risk for transmission of viral diseases, Creutzfeldt-Jakob disease (CJD), and variant Creutzfeldt-Jakob disease (vCJD). No cases of transmission of viral diseases, CJD, or vCJD have ever been identified in other licensed products with the same derivative.

The healthcare professional(s) will record the name and batch number(s) of NUCEIVA used in order to maintain a record of the batch used and trace any possible infection source.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby ask your doctor for advice before you receive this medicine.

The use of NUCEIVA is not recommended during pregnancy and in women able to have children who are not using contraception.

NUCEIVA is not recommended in breast-feeding women.

### Children and adolescents

- The use of NUCEIVA is not recommended in individuals under 18 years.

## 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins, or supplements that you buy without a prescription from your pharmacy, supermarket, or health food shop.

The use of botulinum toxin is not recommended in association with aminoglycoside antibiotics,

spectinomycin, or other medicines that interfere with nerve impulses to the muscle.

**Medicines that may increase the effect of NUCEIVA include:**

- Botox®
- Dysport®
- Xeomin®

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect NUCEIVA.**

## 4. How do I use NUCEIVA?

### How much to inject

- NUCEIVA should only be injected by doctors with appropriate qualifications and expertise in the treatment of frown lines.
- NUCEIVA is injected into your muscles (intramuscularly), directly into the affected area above and between the eyebrows.
- The usual dose of NUCEIVA is 20 Units. You will be injected with the recommended volume of 0.1 millilitre (ml) (4 Units) of NUCEIVA into each of 5 injection sites.
- Unit doses for NUCEIVA are not interchangeable with those used for other preparations of botulinum toxin.
- Improvement of severity of the lines between the eyebrows generally occurs within a few days of treatment.

### When to inject NUCEIVA

- NUCEIVA should not be received more than 1 time every 3 months.
- The interval between treatments will be decided by your doctor.
- Your doctor may change your dose of NUCEIVA, until you and your doctor find the best dose for you.

### If you use too much NUCEIVA

As NUCEIVA is administered by a doctor, it is unlikely that you will receive an overdose. Should accidental injection, oral ingestion, or overdose be suspected, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (by calling **13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.** Symptoms of overdose are likely not to be present immediately following injection.

## 5. What should I know while using NUCEIVA?

### Things you should do

- Remind the doctor, dentist, or pharmacist you visit that you are using NUCEIVA.

### Call your doctor straight away if you:

- Have received any other botulinum toxin product in the last 4 months.

### Things you should not do

- Do not start any new medicines until you have told your doctor that you have received NUCEIVA in the past.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how NUCEIVA affects you.**

NUCEIVA may cause muscle weakness, dizziness, and visual disturbance in some people. Do not drive or use machinery until such effects have cleared.

### Looking after your medicine

- Do not use NUCEIVA after the expiry date which is stated on the vial and carton.
- NUCEIVA should be stored in the refrigerator (2°C - 8°C) at the clinic where the injections are carried out.
- NUCEIVA contains no antimicrobial agent. The product is for the treatment of one patient only on one occasion. Any remaining contents should be discarded appropriately by the clinic.

**Keep it where young children cannot reach it.**

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<b>General:</b> <ul style="list-style-type: none"><li>• Headache</li></ul> <b>Injection site related:</b> <ul style="list-style-type: none"><li>• Bruising</li><li>• Redness</li><li>• Pain</li><li>• Tingling</li></ul> <b>Eye-area related:</b>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

<ul style="list-style-type: none"> <li>• Eyelid drooping</li> <li>• Eyebrow muscle imbalance</li> </ul>	
---	--

## Serious side effects

Serious side effects	What to do
<b>Throat related:</b> <ul style="list-style-type: none"> <li>• Difficulty breathing</li> <li>• Difficulty in swallowing</li> <li>• Difficulty in speaking</li> <li>• Hoarseness, change or loss of voice</li> </ul> <b>Heart related:</b> <ul style="list-style-type: none"> <li>• Irregular heartbeat</li> <li>• Heart attack which may include symptoms such as shortness of breath, feeling weak or faint, and/or chest pain/discomfort in the jaw, neck, back, or in one or both arms or shoulders</li> </ul> <b>Eye related:</b> <ul style="list-style-type: none"> <li>• Blurred vision or double vision</li> <li>• Dry eye or reduced blinking which may result in corneal problems</li> </ul> <b>General body related:</b> <ul style="list-style-type: none"> <li>• Loss of strength all over the body</li> <li>• Loss of bladder control</li> </ul> <b>Allergic reaction related:</b> <ul style="list-style-type: none"> <li>• Significant itching, rash, or hives</li> <li>• Wheezing or trouble breathing</li> <li>• Feeling faint or dizzy</li> </ul>	<b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

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

NUCEIVA should only be injected by doctors with appropriate qualifications and expertise in the treatment of frown lines.

## What NUCEIVA contains

<b>Active ingredient (main ingredient)</b>	prabotulinumtoxinA
<b>Other ingredients (inactive ingredients)</b>	Albumin
<b>Other ingredients (inactive ingredients)</b>	Sodium chloride

**Do not take this medicine if you are allergic to any of these ingredients.**

## What NUCEIVA looks like

NUCEIVA is presented in a clear vial as white to yellowish powder for solution for injection. Each pack contains 1 vial (Aust R 381094).

## Who distributes NUCEIVA

Evolus Australia Pty Ltd  
Suite 2 Level 25  
100 Miller Street  
North Sydney  
NSW 2060

This leaflet was prepared in January 2023.