

# New Zealand Consumer Medicine Information

## RELFYDESS™ (RELL-fih-dess)

Active ingredient: *relabotulinumtoxinA*

### Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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### 1. Why am I receiving RELFYDESS?

RELFYDESS contains the active ingredient *relabotulinumtoxinA* which causes muscles to relax. It works by inhibiting the nerve impulses to the muscles in which it has been injected to prevent muscles from contracting.

RELFYDESS is used in adults to temporarily improve the appearance of moderate to severe vertical frown lines between the eyebrows (glabellar lines) and/or moderate to severe wrinkles at the outer corners of your eyes or crow's feet lines (lateral canthal lines), alone or in combination.

### 2. What should I know before I am given RELFYDESS?

#### Warnings

You should not receive RELFYDESS if:

- you are allergic to RELFYDESS or any botulinum toxin A product, or any of the ingredients listed at the end of this leaflet.
- you are showing signs of infection at the proposed injection site.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if:

- you have any other medical conditions such as:
  - you suffer from certain diseases affecting your nervous system (such as amyotrophic lateral

sclerosis, myasthenia gravis or Eaton Lambert syndrome or other neuromuscular disorders)

- you have difficulties breathing
- you have difficulty swallowing food
- you find that you often have problems with food or drink getting into your airways causing you to cough or choke
- you have a bleeding disorder or blood-thinners as injection may lead to bruising
- you had problems with previous botulinum toxin injections
- you have inflammation at the proposed injection site(s)
- you have eye disorders including drooping eyelids, dry eyes
- you have muscles that are too weak or wasted to be injected

Too frequent or excessive dosing may rarely lead to antibody formation. Antibody formation can stop botulinum toxin type A from working even for other uses. To prevent this, there must be a gap of at least 3 months between doses.

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

Check with your practitioner if you are pregnant or intend to become pregnant.

Talk to your practitioner if you are breastfeeding or intend to breastfeed.

#### Use in Children

RELFYDESS is not recommended for use in patients under the age of 18 years.

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

Tell your practitioner 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.

**Some Medicines that may increase the effect of RELFYDESS include:**

- certain antibiotics for an infection (e.g., aminoglycosides)
- a group of medicines called anticholinergics
- other muscle relaxant drugs
- other medicines containing a botulinum toxin

## 4. How do I use RELFYDESS?

### How much to use

- RELFYDESS should only be administered by trained practitioners with appropriate qualifications and expertise in this treatment and having the required equipment.
- Unit doses for RELFYDESS are not interchangeable with those used for other preparations of botulinum toxin.
- Your practitioner will determine the correct dosage to use, depending on your medical condition.
- The recommended dose for RELFYDESS for the frown lines is 0.5 mL (50 units) by injection into the muscle divided into 5 injections of 0.1 mL each.
- The recommended dose for RELFYDESS for the crow's feet lines is 0.6mL (60 units) by injection into those muscles divided into 6 injections of 0.1mL each.
- The effect of the treatment should be noticeable within a few days after injection and could last for 6 months.
- Your practitioner will determine the correct dosage and to give you and its frequency.

### How long to use RELFYDESS?

- The interval between treatments with RELFYDESS will be decided by your practitioner. You should not have treatment more often than every 3 months.

### If you use too much RELFYDESS

As it is given to you by your practitioner who has received training on administration of RELFYDESS, it is very unlikely that you will receive an overdose.

However, if you are given too much RELFYDESS, muscles other than the ones that were injected may begin to feel weak. Excessive doses may cause paralysis of respiratory muscles.

Symptoms of an overdose may include difficulty in breathing, difficulty in swallowing or difficulty in speaking. This may not happen straight away. If this happens, **immediately telephone your doctor, or the National Poisons Centre (by calling 0800 POISON or 0800 764 766)** if you think you may have been given too much RELFYDESS.

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

### Things you should do

#### Call your doctor straight away if you:

- You have difficulties breathing, swallowing or speaking
- Your face swells or skin goes red, or you get an itchy lumpy rash, this may mean you are having an allergic reaction to RELFYDESS

Remind any doctor, dentist or pharmacist you visit that you are using RELFYDESS.

### Driving or using machines

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

You may experience temporary visual disturbances or muscle weakness following treatment.

### Looking after your medicine

Your medicine will be stored in a refrigerator (2°C - 8°C – do not freeze) in its carton in order to protect from light. If necessary, the vial can be kept at room temperature up to 25°C for a maximum of 24h.

It should not be used after the date marked on the label (expiry date).

Your practitioner will discard any unused medicine appropriately.

## 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
<ul style="list-style-type: none"><li>• Injection site bruise</li><li>• Headache</li><li>• Drooping of the upper eyelid</li><li>• Injection site pain</li><li>• Local muscle weakness around the eyes like drooping of brow</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>• You have difficulties breathing, swallowing or speaking</li><li>• Your face swells or skin goes red, or you get an itchy lumpy rash</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

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions <https://pophealth.my.site.com/carmreportnz/s/>.

By reporting side effects, you can help provide more information on the safety of this medicine.

## 7. Product details

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

### What RELFYDESS contains

<b>Active ingredient (main ingredient)</b>	relabotulinumtoxinA
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• dibasic sodium phosphate dihydrate</li><li>• monobasic sodium phosphate dihydrate</li><li>• potassium chloride</li><li>• sodium chloride</li><li>• polysorbate 80</li><li>• tryptophan</li><li>• water for injections</li></ul>

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

### What RELFYDESS looks like

RELFYDESS is clear, colourless to pale yellow, preservative-free liquid solution, available in a glass vial closed with a rubber stopper and aluminium overseal with plastic cap.

Each vial contains 150 units of relabotulinumtoxinA in 1.5 mL of solution for intramuscular injection.

### Who distributes RELFYDESS

The Sponsor for RELFYDESS is:

Healthcare Logistics  
58 Richard Pearse Drive  
Airport Oaks  
Mangere  
Auckland

Telephone: (09) 9185100

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