RELFYDESS™

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.

1. Why am I receiving RELFYDESS?

RELFYDESS contains the active ingredient relabotulinumtoxinA, which causes muscles to relax. It works by blocking 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 any moderate to severe vertical frown lines between the eyebrows (glabellar lines) and moderate to severe crow's feet lines, wrinkles at the outer corners of your eyes (lateral canthal lines), alone or in combination.

For more information, see Section 1. Why am I using RELFYDESS? in the full CMI.

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

Do not use if you have ever had an allergic reaction to botulinum toxin A or any of the ingredients listed at the end of the CMI. Do not use if you have an infection at the proposed injection sites.

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 am given RELFYDESS? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with RELFYDESS 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 will I be given RELFYDESS?

- RELFYDESS should only be given to you by a practitioner with appropriate qualifications and expertise in this treatment.
- For **frown lines** (glabellar lines) you will be given 50 units (0,5 ml), injected as 10 units (0,1 ml) at each of 5 injection sites in your forehead in the area above your nose and eyebrows.
- For **crow's feet lines** (lateral canthal lines) you will be given 60 units (0,6 ml), injected as 10 units (0,1 ml) at each of 6 injection sites in each of both right and left crow's feet areas.

More instructions can be found in Section 4. How do I use RELFYDESS? in the full CMI.

5. What should I know about being given RELFYDESS?

Things you should do	• Tell your practitioner if you have allergies to any other medicines, preservatives or have an infection at the proposed injection site • Tell your practitioner if you have or have had any of the medical conditions listed in Section 2. What should I know before I am given RELFYDESS? • Tell your doctor if you are pregnant, plan to become pregnant or are breastfeeding
Driving or using machines	• RELFYDESS may temporarily affect the ability to drive or operate machinery. DO NOT drive if you feel you are affected
Looking after your medicine	• RELFYDESS will be stored and administrated by your doctor

For more information, see Section 5. What should I know while about being given RELFYDESS? in the full CMI.

6. Are there any side effects?

Some common side effects associated with RELFYDESS include injection site bruising, headache, drooping of the upper eyelid, injection site pain and local muscle weakness around the eyes like drooping of brow.

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.

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:

1. Why am I receiving RELFYDESS?
2. What should I know before I am given RELFYDESS?
3. What if I am taking other medicines?
4. How am I given RELFYDESS?
5. What should I know about being given RELFYDESS?
6. Are there any side effects?
7. Product details

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 <u>increase</u> 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 Poisons Information Centre (by calling 13 11 26)** 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
• Injection site bruise • Headache • Dizziness • Drooping of the upper eyelid • Injection site pain • Local muscle weakness around the eyes like drooping of brow	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• You have difficulties breathing, swallowing or speaking • Your face swells or skin goes red, or you get an itchy lumpy rash	**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.**

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. 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

Active ingredient (main ingredient)	relabotulinumtoxinA
Other ingredients (inactive ingredients)	• dibasic sodium phosphate dihydrate • monobasic sodium phosphate dihydrate • potassium chloride • sodium chloride • polysorbate 80 • tryptophan • water for injections

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.

AUST R 405864: 1 vial per pack

AUST R 405864: 10 vials per pack

Who distributes RELFYDESS

The Sponsor for RELFYDESS is:
Ipsen Pty Ltd
Level 5, 627 Chapel Street
South Yarra VIC 3141

RELFYDESS is supplied in Australia by:
Galderma Australia Pty Ltd
Level 18, 1 Denison Street,
North Sydney NSW 2060

Telephone: 1800 800 765

This leaflet was prepared in March 2025.