Package leaflet: Information for the user

Relfydess 100 units/mL solution for injection

botulinum toxin type A

▼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. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Relfydess is and what it is used for
2. What you need to know before you use Relfydess
3. How to use Relfydess
4. Possible side effects
5. How to store Relfydess
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1. What Relfydess is and what it is used for

Relfydess contains the active substance botulinum toxin A, 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 to temporarily improve the appearance of moderate to severe vertical lines between the eyebrows (glabellar lines) and moderate to severe lines at the outer corners of your eyes (lateral canthal lines, also known as crow´s feet lines). It is used in adults under 65 years of age in whom those facial lines have an important impact on their well-being.

2. What you need to know before you use Relfydess

Do not have a Relfydess injection if:
- you are allergic to any botulinum toxin or any of the other ingredients of this medicine (listed in section 6).
- you have an infection at the proposed injection sites.
- you have myasthenia gravis, Eaton Lambert syndrome or amyotrophic lateral sclerosis (chronic diseases affecting the muscles)

Warnings and precautions

Talk to your doctor before you have the Relfydess injection if:
- you have any disease affecting your nervous system
- you are debilitated with lack of strength and energy
- you have difficulties breathing
- you have difficulty swallowing food or often have problems with food or drink getting into your airways causing you to cough or choke

- you have had side effects from previous botulinum toxin injections and/or no significant improvement of your lines after your last treatment
- you have inflammation at the proposed injection site(s)
- you have problems with the eyes including drooping eyelids and dry eyes
- the muscles at the proposed injection site are weak or show signs of wasting
- you have a bleeding disorder which means you continue to bleed for longer than normal, or are taking blood thinning medication (anticoagulant)

This information will help your health care professional to make an informed decision about the risk and benefit of your treatment.

Special warnings
Side effects possibly related to the spread of toxin effect away from the site of injection and botulism have been reported very rarely with botulinum toxin (e.g. double vision, blurred vision and / or drooping eyelids, excessive muscle weakness, difficulty swallowing, coughing and choking when swallowing, difficulty speaking or breathing). These symptoms have been reported hours to weeks after the injection.
Seek immediate medical attention if you experience difficulties in swallowing, speaking or breathing.

Use of Relfydess may cause dry eyes. If you experience symptoms of dry eye (e.g., eye irritation, light sensitivity or visual changes) talk to your doctor.

Repeated botulinum toxin treatment can lead to muscle wasting due to the temporary paralysis of the treated muscles.

Too frequent use of botulinum toxins or used at higher doses may lead to antibody formation. The formation of neutralising antibodies may reduce the effectiveness of treatment.

Children and adolescents
Relfydess is not recommended for use in children and adolescents under the age of 18 years.

Other medicines and Relfydess
Tell your doctor if you are using, have recently used or might use any other medicines.
In particular, tell your doctor if you are taking the following medicines, since they may increase the effect of Relfydess:
- certain antibiotics used to treat infections (e.g. aminoglycosides)
- other muscle relaxant medicines
- other medicines containing a botulinum toxin.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.
Relfydess should not be used during pregnancy, if you are of childbearing age and not using contraception or if you are breast-feeding.

Driving and using machines
You may experience temporary visual disturbances or muscle weakness following treatment with Relfydess. If affected, do not drive or use machinery.

Relfydess contains potassium, sodium and polysorbate
This medicine contains potassium, less than 1 mmol (39 mg) per 150 units vial, i.e. essentially ‘potassium-free’.
This medicine contains sodium, less than 1 mmol (23 mg) per 150 units vial, i.e. essentially ‘sodium-free’.
This medicine contains 1.6 mg of polysorbate 80 per 150 units vial which is equivalent to 1.1 mg/mL. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

3. How to use Relfydess

Relfydess should only be given by a health care professional with appropriate qualifications and expertise in this treatment and having the required equipment. Relfydess will be given as injections into the muscles at the intended site.

Unit doses for Relfydess are not interchangeable with those used for other preparations of botulinum toxin.

The recommended dose for Relfydess is:
- ***For vertical lines between the eyebrows***: 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 lines at the outer corner of your eyes***: 60 units (0.6 mL), injected as 10 units (0.1 mL) at each of 6 injection sites. The 6 injection sites include 3 injections in each of both right and left crow's feet areas.
- ***For combined treatment***: same doses are recommended, i.e. 50 units for glabellar lines and 60 units for lateral canthal lines, with a total dose of 110 units (1.1 mL).

The effect of the treatment should be noticeable within a few days after injection and could last for 6 months. The interval between treatments with Relfydess will be decided by your doctor. You should not have treatment more often than every 3 months.

If you receive more Relfydess than you should
As this medicine will be given to you by a health care professional with appropriate qualifications and expertise, it is not likely that you will be given too much of this medicine. If you however are given more Relfydess than you need, muscles other than the ones that were injected may begin to feel weak. Excessive doses may cause swallowing and speech difficulties and breathing problems. This may not happen straight away. If this happens, seek immediate medical attention.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Most side effects are mild to moderate and occur within the first month following injection and are temporary.

Seek urgent medical help if you experience the following symptoms that have been reported very rarely:
- difficulties breathing, swallowing or speaking.
- swelling including swelling of the face or throat, hives, wheezing, feeling faint or shortness of breath. This may mean you are having an allergic reaction to Relfydess.

Tell your doctor if you notice any of the following side effects:

Common (may affect up to 1 in 10 people)
- Injection site reactions like bruising, pain, itching, redness, swelling, discomfort, hypersensitivity, warmth
- Headache
- Drooping of the upper eyelid.

Uncommon (may affect up to 1 in 100 people)
- Muscular weakness
- Muscle twitching
- Drooping of eyebrow
- Allergic reaction, like asthma or widespread nettle rash

- Local allergic reaction, like nettle rash
- Blurred vision
- Dry eyes
- Eye strain
- Swelling of eyelids.

Reporting of side effects
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Relfydess

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C). Do not freeze. Keep the vial in the outer carton in order to protect from light.
Unopened vial may be brought to room temperature at 25°C and protected from light. The stability of Relfydess (unopened vial) has been demonstrated for up to 24 hours at room temperature.

6. Contents of the pack and other information

What Relfydess contains
- The active substance is botulinum toxin type A, 100 units/mL. One vial contains 150 units in 1.5 mL solution.
- The other excipients are: disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate, potassium chloride, sodium chloride, polysorbate 80, tryptophan and water for injections (see section 2 Relfydess contains potassium, sodium and polysorbate).

What Relfydess looks like and contents of the pack
Relfydess is a clear, colourless to pale yellow solution for injection (injection). It comes in pack size of 1 or 10 glass vials containing 1.5 mL solution for injection.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
[to be completed nationally]

Manufacturer
Q-Med AB
Seminariegatan 21
752 28 Uppsala
Sweden

or
Galderma Laboratorium GmbH
Toulouser Allee 23a
40211 Düsseldorf
Germany

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The following information is intended for healthcare professionals only:

Posology and method of administration
Relfydess should only be administered by health care professionals with appropriate qualifications and expertise in this treatment and having the required equipment, in accordance with national guidelines and legislation.

The potency units are specific to Relfydess and are not interchangeable with other preparations of botulinum toxin.

Relfydess is ready-to-use with a concentration of 10 units per 0.1 mL and no reconstitution is required.

Each vial should be used for a single patient during a single treatment session only. Any residual product after the treatment should be discarded.

Table 1: Dosing Instructions for Relfydess

Treatment(s)	Total Recommended Dose	Dose per injection
Glabellar Lines	50 units (0.5 mL)	5 injections of 10 units (0.1 mL): 2 injections on each side at the *corrugator* muscle and 1 injection at the *procerus* muscle near the nasofrontal angle
Lateral Canthal Lines	60 units (0.6 mL)	6 injections of 10 units (0.1 mL): 3 injections on each side at the *orbicularis oculi* muscle
Combined treatment of Glabellar Lines and Lateral Canthal Lines	110 units (1.1 mL)	11 injections total of 10 units (0.1 mL) for combined GL and LCL

Dosing and treatment intervals depend on assessment of the individual patient's response but they should not exceed maximum doses allowed and the minimum interval of 12 weeks.

In order to improve traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Special precautions for disposal and other handling
The instructions for use, handling and disposal should be strictly followed.

RECOMMENDATIONS FOR THE DISPOSAL OF CONTAMINATED MATERIALS
Immediately after use and prior to disposal, unused Relfydess (which may be present in the vial or in the syringe) should be inactivated with diluted sodium hypochlorite solution (0.1 % NaOCl) or sodium hydroxide solution (1 % NaOH). Used vials, syringes and materials should not be emptied and must be discarded into appropriate containers and disposed of in accordance with local requirements.

RECOMMENDATIONS SHOULD ANY INCIDENT OCCUR DURING THE HANDLING OF BOTULINUM TOXIN
- Any spills of the product must be wiped up with dry, absorbent material. The material should be disposed of in accordance with local requirements.
- The contaminated surfaces should be cleaned using diluted hypochlorite or sodium hydroxide solution, then dried.
- If a vial is broken, proceed as mentioned above by carefully collecting the pieces of broken glass and wiping up the product, avoiding any cuts to the skin.
- If the product comes into contact with the skin, wash the affected area with soap and water.
- If product enters into contact with the eyes, rinse thoroughly with plenty of water or with an ophthalmic eyewash solution.

- If product enters into contact with a wound, cut or broken skin, rinse thoroughly with plenty of water and seek medical attention.

These instructions for use handling and disposal should be strictly followed.