

Package leaflet: Information for the patient

Qalsody 100 mg solution for injection tofersen

▼ 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 are given 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, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Qalsody is and what it is used for
2. What you need to know before you are given Qalsody
3. How Qalsody is given
4. Possible side effects
5. How to store Qalsody
6. Contents of the pack and other information

1. What Qalsody is and what it is used for

Qalsody contains the active substance tofersen which belongs to a group of medicines known as *antisense oligonucleotides*.

This medicine is used in adults to treat a type of *amyotrophic lateral sclerosis* (ALS) caused by mutations (changes) in a gene called SOD1.

ALS caused by mutations in the *SOD1* gene is a rare type of motor neuron disease that affects the nerve cells in the brain and spinal cord. Mutations in the SOD1 gene cause a build-up of a toxic form of the SOD1 protein. This causes destruction of motor neurons (the nerve cells responsible for sending instructions to the muscle), leading to weakness and wasting in the muscles, including those used for breathing and swallowing.

Qalsody works by reducing the build-up of SOD1 protein. This helps to prevent the destruction of motor neurons and may slow the loss of muscle strength.

2. What you need to know before you are given Qalsody

Qalsody must not be given

- if you are **allergic to tofersen** or any of the other ingredients of this medicine (listed in section 6).

Talk to your doctor or nurse before you start treatment if this applies to you.

Warnings and precautions

There is a risk of side effects occurring after Qalsody is given by lumbar puncture procedure (see section 3). This can include headaches, back pain and infection.

There have been a small number of reports of patients developing inflammation of the spinal cord (*myelitis*) or irritation or injury to the nerve roots (*radiculitis*) after Qalsody is given. You need to know about the symptoms of this while you are on this medicine. See *Serious side effects* in section 4 of this leaflet.

There have been a small number of reports of patients developing swelling of the optic nerve in the eye (*papilloedema*) and/or an increase in the pressure around the brain (increased intracranial pressure) in patients treated with Qalsody. See *Serious side effects* in section 4 of this leaflet.

Tests before treatment

You may have a **urine test** (to check your kidneys) and a **blood test** (to check that your blood clots properly) before you start treatment. This is because other medicines in the same group as Qalsody can affect the kidneys and the cells in the blood which help clotting. These tests may not be needed every time you are given Qalsody.

Children and adolescents

This medicine should not be given to children and adolescents under 18 years of age. The use of this medicine in patients under age of 18 has not been studied.

Other medicines and Qalsody

Tell your doctor if you are taking, have recently taken or might take any other medicines.

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 you are given this medicine.

Pregnancy

Qalsody is not recommended to be used during pregnancy and in women of childbearing potential not using contraception.

Breast-feeding

Your doctor will help you to decide whether you should continue breast-feeding or to start treatment with Qalsody. Your doctor will consider the possible benefits of treatment for you compared with the benefits of breast-feeding for your baby.

Driving and using machines

This medicine may affect your ability to drive or use machines.

Do not drive or use machines if you notice a change in your vision with Qalsody.

Qalsody contains sodium

This medicine contains 52 mg sodium (main component of cooking/table salt) in each 15 ml. This is equivalent to 3% of the recommended maximum daily dietary intake of sodium for an adult.

Qalsody contains potassium

This medicine contains less than 1 mmol (39 mg) potassium per 15 ml dose, i.e. essentially 'potassium-free'.

3. How Qalsody is given

The recommended dose is 100 mg tofersen. The first three doses will be given at 14-day intervals on day 1, day 15 and day 29 of treatment. Qalsody will then be given every 28 days.

This medicine is given by intrathecal (into the fluid surrounding the spinal cord) injection into the lower back by a lumbar puncture. This is done by inserting a needle into the space around the spinal cord. This will be done by a doctor experienced in doing lumbar punctures.

How long Qalsody is used for

Your doctor will discuss with you how long you will need to receive Qalsody. Do not stop treatment with Qalsody without talking to your doctor.

If you miss a Qalsody injection

If you miss a dose of Qalsody, speak to your doctor so that it can be given as soon as possible.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects related to the lumbar puncture may occur while Qalsody is being given or afterwards. The side effects can include headache, back pain and infection.

Serious side effects

The most serious side effects seen in patients receiving Qalsody have been inflammation of the spinal cord (*myelitis*) or irritation and injury of nerve roots (*radiculitis*). Common symptoms may include:

- weakness
- numbness
- abnormal sensations (pins and needles)
- pain.

Swelling of the nerve that connects the eyes with the brain (*papilloedema*) and increased pressure around your brain (increased intracranial pressure) have also been reported. Papilloedema can result from increased intracranial pressure. Common symptoms may include:

- blurred vision
- double vision
- vision loss
- headache.

Inflammation of the lining around the brain and spinal cord (*aseptic or chemical meningitis*) has been reported. This is not caused by an infection. Common symptoms may include:

- headache
- fever
- neck stiffness
- nausea
- vomiting.

Tell your doctor immediately, if you have any of the symptoms listed above.

Other side effects

Very common (*may affect more than 1 in 10 people*)

- pain (back pain, pain in arms or legs)
- feeling tired
- muscle and joint pain
- fever
- increase in protein and/or white blood cell count occurring in the fluid that surrounds the brain and spinal cord.

Common (*may affect up to 1 in 10 people*)

- muscle stiffness
- nerve pain, including burning, stabbing, pins and needles sensations.

Tell your doctor if you notice these or any new symptoms that concern you.

Reporting of side effects

If you get any side effects, talk to your **doctor, pharmacist or nurse**. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Qalsody

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 carton after EXP. The expiry date refers to the last day of that month.

Do not use this medicine if you notice particles in the solution or if the liquid in the vial is not clear and colourless.

Store in a refrigerator (2°C - 8°C). Do not freeze.

Keep the vial in the outer carton in order to protect from light.

The vial of Qalsody in its original carton can be stored for up to 14 days at room temperature (store below 30°C).

Unopened vials of Qalsody can be removed from and returned to the refrigerator, if necessary.

Unopened vials can be removed from the original carton for not more than 6 hours per day at room temperature for a maximum of 6 days.

6. Contents of the pack and other information

What Qalsody contains

- The active substance is tofersen
- Each 15 ml vial contains 100 mg of tofersen.
- Each ml contains 6.7 mg of tofersen.
- The other ingredients are disodium phosphate, potassium chloride, calcium chloride dihydrate, magnesium chloride hexahydrate, sodium chloride, sodium dihydrogen phosphate dihydrate, water for injections.

What Qalsody looks like and contents of the pack

Qalsody is a clear, colourless to slightly yellow solution for injection.

Each carton of Qalsody contains one vial.

Marketing Authorisation Holder and Manufacturer

Biogen Netherlands B.V.
Prins Mauritslaan 13
1171 LP Badhoevedorp
The Netherlands

For information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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This medicine has been authorised under 'exceptional circumstances'. This means that because of the rarity of this disease it has been impossible to get complete information on this medicine. The Medicines and Healthcare products Regulatory Agency (MHRA) will review any new information on this medicine every year and this leaflet will be updated as necessary.'

This leaflet was last revised in May 2025

Other sources of information

For information in large print, CD or Braille please contact 0800 008 7401.