

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 being given QALSODY?

QALSODY contains the active ingredient tofersen. QALSODY is used in adults to treat the type of amyotrophic lateral sclerosis (ALS) caused by an altered superoxide dismutase 1 (SOD1) gene. This is a rare type of motor neuron disease. For more information, see Section [1. Why am I using QALSODY?](#) in the full CMI.

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

Do not use if you have ever had an allergic reaction to QALSODY or any of the ingredients listed at the end of the CMI. **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 QALSODY?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with QALSODY and affect how it works. Additional information is found in Section 3. What if I am taking other medicines? in the full CMI.

4. How QALSODY is given?

- The recommended dose of QALSODY is 100 mg.
- QALSODY is administered by an experienced doctor as an injection into the lower back (called a lumbar puncture).

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

5. What should I know while you are given QALSODY?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using QALSODY. • There have been a small number of reports of patients developing inflammation of the spinal cord (myelitis) or irritation or inflammation of the nerve roots (radiculitis) after QALSODY is given. You need to know about the symptoms of this while you are on this medicine. • 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
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how QALSODY affects you.
Drinking alcohol	• Tell your doctor if you drink alcohol.
Looking after your medicine	• Refrigerate do not freeze. • Keep the vial in the outer carton in order to protect it from light. • QALSODY is usually stored in the hospital pharmacy until it is time for it to be given to you.

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

6. Are there any side effects?

Common side effects may include: pain (back pain, pain in arms or legs), increase in protein and/or white blood cell count occurring in the fluid that surrounds the brain and spinal cord, feeling tired, muscle and joint pain, fever, muscle stiffness or nerve pain. Serious side effects may include: inflammation of the spinal cord (myelitis), irritation or inflammation of nerve roots (radiculitis), swelling of the optic nerve in the eye (papilloedema), increased pressure around the brain (increased intracranial pressure) or inflammation of the lining around the brain and spinal cord (aseptic meningitis). 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.

QALSODY™ (phonetic pronunciation - kal soe' dee)

Active ingredient(s): tofersen 100 mg solution for injection

This medicine has **provisional approval** in Australia for the treatment of adults with amyotrophic lateral sclerosis (ALS) caused by a mutation in the superoxide dismutase 1 (SOD1) gene. The decision to approve this medicine has been made on the basis of data available at the time of provisional approval, including efficacy, safety and biomarker results. Continued approval for this indication depends on additional data.

Consumer Medicine Information (CMI)

This leaflet provides important information about using QALSODY. **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 QALSODY.**

Where to find information in this leaflet:

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

1. Why am I being given QALSODY?

QALSODY contains the active ingredient tofersen.

QALSODY belongs to a group of medicines known as antisense oligonucleotides (ASOs).

QALSODY is used in adults to treat the type of amyotrophic lateral sclerosis (ALS) caused by an altered superoxide dismutase 1 (SOD1) gene. This is a rare type of motor neuron disease.

The altered gene causes a build-up of toxic SOD1 protein. This causes loss of nerve cells in the brain and spine, leading to weakness in muscles, including those used for breathing and swallowing.

QALSODY works by reducing the build-up of SOD1 protein. This helps to prevent the loss of nerve cells and may slow the loss of muscle strength.

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

Warnings

Do not use QALSODY if:

- you are allergic to tofersen, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions.
- take any medicines for any other condition.

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?](#)

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.

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 are given this medicine.

Pregnancy

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

Breastfeeding

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

Children and adolescents

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

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.

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

4. How QALSODY is given?

How much to use

- The recommended dose of QALSODY is 100 mg.

- While you are receiving QALSODY, please follow any instructions provided by your doctor.
- Your doctor will tell you how long you will need to receive QALSODY. Do not stop treatment with QALSODY unless your doctor tells you to.

When to use QALSODY

- Treatment is given:
- on the first day, day 1
- then on day 15 and day 29
- then once every 28 days.

How to use QALSODY

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

If you miss a QALSODY injection

QALSODY should be used regularly. If you miss your dose at the usual time, speak to your doctor so that it can be given as soon as possible.

If you are given too much QALSODY

No cases of overdose associated with QALSODY were reported in clinical trials.

Your doctor is trained to calculate the correct dose and administer your medicine.

If you think that you have been given too much QALSODY, 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.

5. What should I know while you are given QALSODY?

Things you should do

- There have been a small number of reports of patients developing inflammation of the spinal cord (myelitis) or irritation or inflammation of the nerve roots (radiculitis) after QALSODY is given. You need to know about the symptoms of this while you are on this medicine. See Inflammation of spinal cord or nerve in section [6. Are there any side effects](#) 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 section [6. Are there any side effects](#) of this leaflet.

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

Driving or using machines

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

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.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

QALSODY is usually stored in the hospital pharmacy until it is time for it to be given to you.

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
Bones, muscles and joints-related: • Muscle and joint pain • Muscle stiffness Nervous system-related: • Increase in protein and/or white blood cell count occurring in the fluid that surrounds the brain and spinal cord • Nerve pain with symptoms that may include burning, stabbing, pins-and-needles sensations, numbness Lumbar-puncture-related: There may be side effects which are due to the lumbar puncture and which some people experience during or shortly after QALSODY is given. These can include: • back pain • headache • swelling, bruising or pain at the injection site Other: • Fever • Feeling tired • Pain (back pain, pain in arms or legs)	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
Nervous system-related: • Inflammation of the spinal cord (myelitis, including myelitis transverse and neurosarcoidosis) • Irritation or inflammation of nerve roots (radiculitis, including radiculopathy and lumbar radiculopathy) Common symptoms may include but are not limited to weakness, numbness, abnormal sensations (pins-and-needles) or pain. • Swelling of the optic nerve in the eye (papilloedema) and increased pressure around the brain (increased intracranial pressure) This nerve connects the eyes with the brain and is responsible for vision. Common symptoms may include but are not limited to blurred vision, double vision or vision loss. • Inflammation of the lining around the brain and spinal cord (aseptic meningitis) Aseptic or chemical meningitis is inflammation of the lining around the brain or the spinal cord. It is not caused by an infection. Symptoms may include but are not limited to headache, fever, neck stiffness, nausea or vomiting.	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.

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.

What QALSODY contains

Active ingredient (main ingredient)	tofersen
Other ingredients (inactive ingredients)	Dibasic sodium phosphate Potassium chloride Calcium chloride dihydrate Magnesium chloride hexahydrate Sodium chloride Sodium dihydrogen phosphate dihydrate Water for injection
Potential allergens	None

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

What QALSODY looks like

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

Each carton of QALSODY contains one vial. Each vial is for a single use.

Each vial of 15 mL contains 100 mg of tofersen.

(Aust R 467305).

Who distributes QALSODY

Biogen Australia Pty Ltd

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Australia

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