

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried for you or your child about using this medicine, speak to your doctor, nurse or pharmacist.

1. Why am I using SPINRAZA?

SPINRAZA has nusinersen (as heptadecasodium) as active ingredient. SPINRAZA is used to treat the genetic disease called Spinal Muscular Atrophy (SMA).

For more information, see Section [1. Why am I using SPINRAZA?](#) in the full CMI.

2. What should I know before I use SPINRAZA?

Do not use if you have ever had an allergic reaction to SPINRAZA or any of the ingredients listed at the end of the CMI.

Talk to your doctor or nurse if you or your child 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 SPINRAZA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with SPINRAZA 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 do I use SPINRAZA?

- The usual dose of SPINRAZA is 12 mg administered by an experienced doctor, and given as a continuous injection (over 1 to 3 minutes) into the lower back by lumbar puncture.
- Your doctor may give you or your child a medicine to make you or your child relax or sleep (sedation) before giving SPINRAZA.

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

5. What should I know while using SPINRAZA?

Things you should do	<ul style="list-style-type: none">• Keep all of your or your child's hospital, doctor and physiotherapy appointments so that you or your child's progress can be checked.• Remind any doctor, dentist, nurse or pharmacist you or your child visit that you are receiving SPINRAZA.
Things you should not do	<ul style="list-style-type: none">• Do not stop receiving this medicine without consulting your doctor.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how SPINRAZA affects you.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">• SPINRAZA is usually stored in the hospital pharmacy until it is time for it to be given to you or your child.

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

6. Are there any side effects?

Side effect may include infections, allergic reactions, gut, skin or breathing related effects. You or your child might experience side effects caused by the lumbar puncture procedure.

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.

SPINRAZA

Active ingredient(s): nusinersen (as heptadecasodium) 12mg/5mL solution for injection

Consumer Medicine Information (CMI)

This leaflet provides important information about using SPINRAZA. **You should also speak to your doctor, nurse or pharmacist if you would like further information or if you have any concerns or questions about using SPINRAZA.**

Where to find information in this leaflet:

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

1. Why am I using SPINRAZA?

SPINRAZA contains the active ingredient nusinersen (as heptadecasodium). SPINRAZA is a type of medicine called an anti-sense oligonucleotide (ASO).

SPINRAZA is used to treat the genetic disease called Spinal Muscular Atrophy (SMA).

Spinal Muscular Atrophy (SMA) is a genetic disease caused by a shortage of a protein called survival motor neuron (SMN). This results in the loss of nerve cells in the spine, leading to weakness of the muscles in the shoulders, hips, thighs and upper back. It may also weaken the muscles used for breathing and swallowing.

SPINRAZA works by causing the body to produce more SMN protein.

SPINRAZA has only been proven to work in a type of SMA known as 5q SMA.

Ask your doctor if you have any questions about why this medicine has been prescribed for you or your child.

Your doctor may have prescribed it for another reason.

There is no information on the use of this medicine in adults above 18 years of age.

This medicine is not addictive.

It is available only with a doctor's prescription.

This medicine is given to you or your child by a doctor.

2. What should I know before I use SPINRAZA?

Warnings

Do not use SPINRAZA if:

you or your child have an allergy to:

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

Some of the symptoms of an allergic reaction may include:

- shortness of breath.
- wheezing or difficulty breathing.
- swelling of the face, lips, tongue or other parts of the body.
- rash, itching or hives on the skin.

If any of these signs occur, stop using SPINRAZA and notify your doctor, nurse or pharmacist immediately.

- Do not receive this medicine after the expiry date printed on the vial or if the packaging is torn or shows signs of tampering.**

If you receive it after the expiry date has passed, it may not work as intended.

- Do not receive SPINRAZA if the medicine is cloudy, contains particles or is discoloured.**

It should be clear and colourless.

- If you are not sure whether you or your child should start receiving this medicine, talk to your doctor.**

Check with your doctor if you or your child:

- have bleeding problems, problems with blood clotting, or low platelet counts.
- Tell your doctor if you or your child have kidney problems.
- Tell your doctor if you or your child have allergies to any other medicines, foods, preservatives or dyes.

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

Tell your doctor if you are pregnant or intend to become pregnant.

There is no information on the use of SPINRAZA during pregnancy. Your doctor will discuss the risks and benefits of receiving it if you are pregnant.

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

It is not known whether SPINRAZA passes into breast milk. Your doctor will discuss the risks and benefits of receiving it if you are breast-feeding.

3. What if I am taking other medicines?

Tell your doctor, nurse 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.

Your doctor and nurse have more information on medicines to be careful with or avoid while taking this medicine.

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

4. How do I use SPINRAZA?

How much to use

- The usual dose of SPINRAZA is 12 mg, given as a continuous injection into the lower back (over 1 to 3 minutes) by lumbar puncture.

When to use SPINRAZA

- You or your child will usually be given SPINRAZA on the first day of treatment then again approximately 14, 28 and 63 days later. After this, SPINRAZA is given once every 4 months.
- **Continue receiving your medicine for as long as your doctor tells you.**
Your doctor will tell you how long you or your child needs to keep having SPINRAZA.

How to give SPINRAZA

- SPINRAZA 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. Your doctor may give you or your child a medicine to make you or your child relax or sleep (sedation) before giving SPINRAZA.

If you or your child forget to use SPINRAZA

SPINRAZA should be used regularly. If you or your child miss your dose at the usual time, talk to your doctor or nurse as soon as possible.

If you or your child are unable to receive SPINRAZA as planned, speak with your doctor to ensure that SPINRAZA can be given as soon as possible.

If you use too much SPINRAZA

There have been no reported overdoses of SPINRAZA.

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

If you think that you or your child have been given too much SPINRAZA, you may need urgent medical attention.

You should immediately:

- phone the Australian Poisons Information Centre (**by calling 13 11 26**), or the New Zealand National Poisons Information Centre (**by calling 0800 POISON or 0800 764 766**), 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 using SPINRAZA?

Things you should do

Keep all of your or your child's hospital, doctor and physiotherapy appointments so that you or your child's progress can be checked.

Remind any doctor, nurse, dentist or pharmacist you visit that you or your child are using SPINRAZA.

Things you should not do

- Do not stop using this medicine without consulting your doctor.
- Do not give your or your child's medicine to anyone else, even if they appear to have the same condition as you.

Driving or using machines

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

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

SPINRAZA is usually stored in the hospital pharmacy until it is time for it to be given to you or your child.

However, if you need to store SPINRAZA:

Follow the instructions in the carton on how to take care of your medicine properly.

- Keep SPINRAZA in the original carton until it is time for it to be given.
- Keep it in the refrigerator, between 2°C and 8°C. Do not freeze. Protect from light.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

Each vial of SPINRAZA should be used once only. The doctor, nurse or pharmacist will discard any unused portion.

Do not use this medicine after the expiry date.

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, nurse or pharmacist if you have any further questions about side effects.

In studies with SPINRAZA the side effects are consistent with the signs and symptoms of SMA or are side effects which can occur when medications are given by lumbar puncture.

There is a risk of side effects occurring after SPINRAZA is given by a lumbar puncture procedure.

This can include headaches, vomiting, back pain and infection. There may also be difficulties with giving a medicine by this method in very young patients and those with scoliosis (twisted and curved spine).

You or your child may be at risk of bleeding complications whilst receiving treatment with SPINRAZA. Before you or your child are given SPINRAZA your doctor may decide to do a blood test to check that your or your child's blood can clot properly.

Your doctor may decide to repeat this test from time to time whilst you or your child are given SPINRAZA.

SPINRAZA may affect the kidneys. Before you or your child are given SPINRAZA your doctor may decide to do a urine test to check that your or your child's kidneys are working normally. This may not be required every time you or your child are given SPINRAZA.

You or your child should be aware that symptoms and signs of SMA may still occur when being treated with SPINRAZA, e.g. breathing problems, muscle weakness, joint and bone problems, or digestive problems.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> infections of the airways due to viruses such as the cold virus including symptoms such as a blocked, stuffy or runny nose, sneezing and coughing, a sore or scratchy throat and watery or itchy eyes infections in the ears leading to painful ears or loss of balance (Otitis media) heart-burn (Gastro-esophageal reflux disease) diarrhoea stiffness of muscles or joints, curving of the back or spine, pain <p>There may be side effects which are due to the lumbar puncture and which some people experience during or shortly after SPINRAZA is given. These can include:</p> <ul style="list-style-type: none"> back-pain headache feeling or being sick (nausea or vomiting) swelling or pain at the injection site 	<p>Speak to your doctor, nurse or pharmacist if you or your child have any of these less serious side effects and they worry you.</p> <p>These are less common side effects.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> increase in heart rate bluish-tinge of the skin, fingertips or lips infections of the lungs such as pneumonia infections of the nose, sinuses, throat, airways or lungs such as respiratory tract infections, bronchitis constipation feeling or being sick (nausea or vomiting) difficulty or being unable to swallow rash fever cough nose bleed 	<p>Tell your doctor, nurse or pharmacist immediately if you notice any of the following happening to you or your child and they worry you.</p> <p>If any of these persist or worsen, talk to your doctor.</p> <p>These are very common side effects.</p>
<ul style="list-style-type: none"> swelling of the face, lips, tongue or other parts of the body, rash, itching or hives which may be an allergic or allergic-like reaction shortness of breath, wheezing, difficulty breathing including rapid or shallow breathing, chest pain or discomfort confusion or loss of consciousness fever, vomiting, headache, stiff neck (which may be symptoms of a serious infection and/or aseptic meningitis) in babies and children, an increase in head size which may appear to worsen over a short period of time 	<p>Go straight to the Emergency Department at your nearest hospital if you or your child notice any of these serious side effects. Notify your doctor.</p> <p>These are very serious side effects.</p> <p>You or your child may need urgent medical attention or hospitalisation. These side effects are very rare.</p>

Tell your doctor, nurse or pharmacist if you notice anything else that may be making you or your child 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 SPINRAZA contains

Active ingredient (main ingredient)	nusinersen (as heptadecasodium)
Other ingredients (inactive ingredients)	sodium chloride potassium chloride calcium chloride dihydrate magnesium chloride hexahydrate dibasic sodium phosphate sodium phosphate monobasic dihydrate sodium hydroxide hydrochloric acid water for injection
Potential allergens	None

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

What SPINRAZA looks like

SPINRAZA comes as a clear and colourless solution in a glass vial. Each pack of SPINRAZA contains 12mg nusinersen (as heptadecasodium) in 5mL of solution in a single 5mL vial.

SPINRAZA is only available in one pack size.

SPINRAZA is usually drawn up into a syringe ready for your or your child's dose to be given by a doctor.

SPINRAZA - AUST R 282522.

Further information

You can obtain more information from your doctor, pharmacist or nurse or by telephoning 1800 852 289 in Australia or 0800 852 289 in New Zealand.

Who distributes SPINRAZA

SPINRAZA is supplied in Australia by:

Biogen Australia Pty Ltd
Level 4, 2 Banfield Road
Macquarie Park, NSW 2113
Australia

SPINRAZA is supplied in New Zealand by:

Biogen NZ Biopharma Limited
188 Quay Street
Auckland
New Zealand

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