

SPINRAZA®

nusinersen (as heptadecasodium) 12mg/5mL solution for injection

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SPINRAZA. It does not contain all the available information. It does not take the place of talking to your doctor, pharmacist or nurse.

This leaflet was last updated on the date at the end of this leaflet.

Speak to your pharmacist or doctor to obtain the most up to date information on this medicine.

You can also download the most up to date leaflet from:

www.biogen.com.au/products/SPINRAZA-CMI.pdf

All medicines have risks and benefits. Your doctor has weighed the risks of you or your child receiving SPINRAZA against the benefits they expect it will have.

If you have any concerns about you or your child receiving this medicine, ask your doctor, pharmacist or nurse.

Keep this leaflet with the medicine.

You may need to read it again.

What SPINRAZA is used for

SPINRAZA is a type of medicine called an anti-sense oligonucleotide (ASO). It 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.

Before you or your child is given SPINRAZA

When you or your child must not be given it

Do not receive SPINRAZA if you or your child have an allergy to:

- SPINRAZA and/or
- any of the ingredients listed at the end of this leaflet.

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 or nurse 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 well.

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.

Before you or your child are given it

Tell 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.

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.

Tell your doctor if you are breast-feeding or planning to breast-feed.

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.

If you have not told your doctor about any of the above, tell them before you or your child start receiving SPINRAZA.

Taking other medicines

Tell your doctor or nurse if you are taking any other medicines, including any that you get 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.

How SPINRAZA is given

How it is given

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.

How much is given

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

When it is given

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.

How long to receive it

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.

If you or your child miss a dose

Talk to your doctor as soon as possible if you or your child miss a dose.

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 are given too much (overdose)

There have been no reported overdoses of SPINRAZA.

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

If you think you or your child have been given too much, contact your doctor or the Poisons Information Centre (in Australia telephone 13 11 26 or in New Zealand 0800 POISON or 0800 764 766) for advice.

While you or your child are being given SPINRAZA

Things you must 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.

Tell any other doctors, dentists and pharmacists who treat you that you or your child are being treated with this medicine.

Things you must not do

Do not give your or your child's medicine to anyone else, even if

they appear to have the same condition as you.

Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You or your child may need medical attention if you or your child get some of the side effects.

Do not be alarmed by the following lists of side effects. You or your child may not experience any of them.

Tell your doctor, pharmacist or nurse as soon as possible if you or your child do not feel well while you or your child are being given SPINRAZA.

Ask your doctor, pharmacist or nurse to answer any questions you may have.

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.

Tell your doctor, pharmacist or nurse immediately if you notice any of the following happening to you or your child and they worry you:

- 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.

The above list includes the very common (may affect more than 1 in 10 people) and common (may affect up to 1 in 10 people) side effects that were seen in patients treated with SPINRAZA in clinical trials in patients who had symptoms of SMA.

If any of these persist or worsen, talk to your doctor.

Tell your doctor, pharmacist or nurse if you notice any of the following happening to you or your child and they worry you:

- 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.

The above list includes less common side effects.

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:

- back-pain
- headache
- feeling or being sick (nausea or vomiting)
- swelling or pain at the injection site.

Tell your doctor if you or your child experience any of these symptoms.

If any of the following happen to you or your child, tell your doctor or nurse immediately or go to Emergency at your nearest hospital:

- 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.

The above list includes very serious side effects. You or your child may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor, pharmacist or nurse if you notice anything that is making you or your child feel unwell.

After receiving SPINRAZA

If you have any queries about any aspect of this medicine, or any questions regarding the information in this leaflet, discuss them with your doctor, nurse or pharmacist.

Storage

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:

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

Disposal

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

Product description

What it looks like

SPINRAZA comes as a clear and colourless solution in a glass vial. Each pack of SPINRAZA contains 12mg nusinersen 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.

Ingredients

SPINRAZA contains nusinersen (as heptadecasodium) as the active ingredient.

Other 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.

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.

Sponsor

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
Auckland

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