Package leaflet: Information for the user

Spinraza 28 mg solution for injection
Spinraza 50 mg solution for injection

nusinersen

Read all of this leaflet carefully before you or your child receives 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 nurse.
- If you or your child gets any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Spinraza is and what it is used for

Spinraza contains the active substance *nusinersen* which belongs to a group of medicines known as *antisense oligonucleotides*. Spinraza is used to treat a genetic disease called *spinal muscular atrophy* (SMA).

Spinal muscular atrophy is caused by a shortage of a protein called *survival motor neuron* (SMN) in the body. 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 helping the body to produce more of the SMN protein that people with SMA are lacking. This reduces the loss of nerve cells and so may improve muscle strength.

2. What you need to know before you or your child are given Spinraza

Spinraza must not be given
- If you or your child are **allergic to nusinersen** or any of the other ingredients of this medicine (listed in section 6).

If you are not sure, talk to your doctor or nurse before you or your child are given Spinraza.

Warnings and precautions
There is a risk of side effects occurring after Spinraza is given by a lumbar puncture procedure (see section 3). This can include headaches, vomiting and back pain. There may also be difficulties with giving a medicine by this method in very young patients and those with scoliosis (twisted and curved spine).

Other products that are in the same group of medicines as Spinraza have been shown to affect the cells in the blood which help clotting. 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. This may not be required every time you or your child are given Spinraza.

Other products that are in the same group of medicines as Spinraza have been shown to 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.

There have been a small number of reports of patients developing hydrocephalus (a build-up of too much fluid around the brain) after Spinraza is given. Some of these patients had needed to have a device called a ventriculo-peritoneal shunt implanted to treat the hydrocephalus. If you notice any symptoms of increase in head size, decreased consciousness, persistent nausea, vomiting or headache; or other symptoms that cause you concern, please inform your or your child's doctor to seek necessary treatment. The benefits and risks of continuing Spinraza whilst having a "ventriculo-peritoneal shunt" in place are not known at present.

Talk to your doctor before you or your child are given Spinraza.

Other medicines and Spinraza
Tell your doctor if you or your child are taking, have recently taken any, or might take any other medicines in future.

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 being given this medicine. It is preferable to avoid the use of Spinraza during pregnancy and breast-feeding.

Driving and using machines
Spinraza has no or negligible influence on the ability to drive and use machines.

Spinraza contains a small amount of sodium
This medicine contains less than 1 mmol sodium (23 mg) per 5 ml vial, that is to say essentially 'sodium-free' and can be used by people on a sodium-restricted diet.

Spinraza contains a small amount of potassium
This medicine contains potassium, less than 1 mmol (39 mg) per 5 ml vial, i.e. essentially 'potassium-free'.

3. How Spinraza is given

If you have never been treated with Spinraza:
- A dose of Spinraza 50 mg is given on day 0 and then on day 14.
- Then Spinraza 28 mg is given once every 4 months.

If you have been treated with Spinraza 12 mg and your physician decides to give you the 50 mg and 28 mg doses:
- One dose of Spinraza 50 mg is given at least 4 months after the last dose of 12 mg
- Then Spinraza 28 mg is given once every 4 months.

Spinraza is given by injection into the lower back. This injection, called a lumbar puncture, 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. You or your child may also be given a medicine to make you relax or sleep during the procedure.

How long to use Spinraza
Your doctor will tell you how long you or your child need to receive Spinraza. Don't stop treatment with Spinraza unless your doctor tells you to.

If you or your child misses an injection
If you or your child miss a dose of Spinraza, speak with your doctor so that Spinraza can be given as soon as possible.

If you have any questions about how Spinraza is given, ask your doctor.

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 Spinraza is being given or afterwards. The majority of these side effects are reported within 72 hours of the procedure.

Very common (may affect more than 1 in 10 people)
- Back pain
- Headache
- Vomiting
- Fever (high temperature)

Not known (frequency cannot be estimated from the available data)
- Serious infection related to lumbar puncture (e.g. meningitis)
- Hydrocephalus (a build-up of too much fluid around the brain)
- Meningitis not caused by an infection (inflammation of the membrane around the spinal cord and brain, which may present as neck stiffness, headache, fever, nausea and vomiting)
- Hypersensitivity (an allergic or allergic-like reaction that may include swelling of your face, lips or tongue, rash, or itching)
- Arachnoiditis (an inflammation of a membrane surrounding the brain and spinal cord), which can cause pain in the lower back, or pain, numbness or weakness in the legs.

Reporting of side effects
If you or your child get any side effects, talk to your doctor 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 Spinraza

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

Store in a refrigerator (2°C to 8°C). Do not freeze.
Keep the vial in the outer carton in order to protect from light.
If no refrigeration is available, Spinraza may be stored in its original carton, protected from light at or below 30°C for up to 14 days.

Unopened vials of Spinraza can be removed from and returned to the refrigerator if necessary. If removed from the original carton, the total time out of refrigeration should not exceed 30 hours, at a temperature that does not exceed 25°C.

Medicines should not be disposed of via wastewater or household waste. Your healthcare professional will throw away any medicines that are no longer being used. These measures will help protect the environment.

6. Contents of the pack and other information

What Spinraza contains
- The active substance is nusinersen.

Spinraza 28 mg
- Each 5 ml vial contains nusinersen sodium equivalent to 28 mg nusinersen.
- Each ml contains 5.6 mg of nusinersen.

Spinraza 50 mg
- Each 5 ml vial contains nusinersen sodium equivalent to 50 mg nusinersen.
- Each ml contains 10 mg of nusinersen.

The other ingredients are sodium dihydrogen phosphate dihydrate, disodium phosphate, sodium chloride (see section 2 “Spinraza contains a small amount of sodium”), potassium chloride (see section 2 “Spinraza contains a small amount of potassium”), calcium chloride dihydrate, magnesium chloride hexahydrate, sodium hydroxide, hydrochloric acid, water for injections.

What Spinraza looks like and contents of the pack
Spinraza is a clear, colourless solution for injection.
Each carton of Spinraza contains one vial.
Each vial is for single use in one patient only. Do not dilute.

Marketing Authorisation Holder and Manufacturer
Biogen Netherlands B.V.
Prins Mauritslaan 13
1171 LP Badhoevedorp
The Netherlands

This leaflet was last revised in December 2025

<--->

The following information is intended for healthcare professionals only:

1. The Spinraza vial should be inspected for particles prior to administration. If particles are observed and/or the liquid in the vial is not clear and colourless, the vial must not be used.

2. Aseptic technique should be used when preparing Spinraza solution for intrathecal administration.

3. The vial should be taken out of the refrigerator and allowed to warm to room temperature (25°C) without using external heat sources, prior to administration.

4. If the vial remains unopened and the solution is not used, it should be returned to the refrigerator.

5. Just prior to administration, remove the plastic cap and insert the syringe needle into the vial through the center of the over-seal to remove the appropriate volume. Spinraza must not be diluted. The use of external filters is not required.

6. Spinraza is administered as an intrathecal bolus injection over 1 to 3 minutes, using a spinal anaesthesia needle.

7. The injection must not be administered in areas of the skin where there are signs of infection or inflammation.

8. It is recommended that the volume of CSF, equivalent to the volume of Spinraza to be injected, is removed prior to administration of Spinraza.

9. Once drawn into the syringe, if the solution is not used within 6 hours, it must be discarded.

10. Any unused product in the vial should be discarded and waste material must be disposed of in accordance with local requirements.