

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrSPINRAZA

nusinersen injection

Read this carefully before you or your child start receiving **SPINRAZA** and each time you receive a dose. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about you or your child's medical condition and treatment and ask if there is any new information about **SPINRAZA**.

What is SPINRAZA used for?

SPINRAZA is used to treat a genetic disease called 5q Spinal Muscular Atrophy (SMA). SMA is caused by a problem with the 5q chromosome. This problem leads to a shortage of a particular protein called survival motor neuron (SMN). The shortage of SMN protein results in the loss of nerve cells in the spine that leads 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 may be given to children, adolescents or adults:

- There is limited experience of SPINRAZA in people over 18 years of age.
- There is no experience of SPINRAZA in people over 65 years of age.

How does SPINRAZA work?

SPINRAZA belongs to a group of medicines called anti-sense oligonucleotides (ASO). SPINRAZA works by helping the body to produce more of the SMN protein that people with SMA need. This may reduce the loss of nerve cells and improve muscle strength.

What are the ingredients in SPINRAZA?

Medicinal ingredients: nusinersen

Non-medicinal ingredients: calcium chloride dihydrate, disodium phosphate, magnesium chloride hexahydrate, potassium chloride, sodium chloride, sodium dihydrogen phosphate dihydrate, water for injection. Sodium hydroxide and hydrochloric acid may be used for pH adjustment.

SPINRAZA comes in the following dosage forms:

Solution for intrathecal (lower spinal cord) injection: 2.4 mg/mL

Do not use SPINRAZA if:

- You or your child are allergic to nusinersen or to any of the other ingredients in SPINRAZA or its container.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you or your child are given SPINRAZA. Talk about any health conditions or problems you may have, including if you/your child:

- have known reasons why you or your child should not have a lumbar puncture (lower spinal cord injection). These may include:
 - a skin infection near the site of the lumbar puncture;
 - increased pressure within the skull;
 - uncontrolled problems with blood clotting;
 - recent injury or damage to the spinal cord.
- have a ventriculo-peritoneal shunt (a small tube that helps drain extra cerebrospinal fluid from the brain). It is used to treat hydrocephalus (buildup of fluid in the brain).
- have been told by a healthcare professional that you/your child have low levels of platelets in the blood.
- have kidney problems.
- are pregnant, think you might be pregnant or are planning to have a baby.
- are breastfeeding or are planning to breastfeed.

Other warnings you should know about:

SPINRAZA can cause serious side effects, including:

- **Blood clotting problems and risk of bleeding:** After receiving medicines similar to SPINRAZA, some patients had:
 - low levels of platelets (blood cells that help stop bleeding) that came and went without affecting blood clotting;
 - severely low levels of platelets;
 - abnormal blood clotting.You or you child may be at risk of bleeding complications during treatment with SPINRAZA.
- **Hydrocephalus** (buildup of fluid in the brain): In patients treated with SPINRAZA there have been reports of hydrocephalus that were not due to bleeding or meningitis (inflammation of the protective membranes of the brain and spinal cord). If you or your child experience signs or symptoms of hydrocephalus during treatment with SPINRAZA, **seek immediate medical attention**. You/your child may require treatment with a ventriculo-peritoneal shunt (a small tube that helps drain extra cerebrospinal fluid from the brain).
- **Kidney toxicity** (damage to the kidneys): After receiving medicines similar to SPINRAZA, some patients had:
 - higher levels of protein in their urine;
 - an increased risk of toxicity in the kidneys;
 - inflammation of the kidneys, which has caused death.

SPINRAZA was also found in high concentrations in the kidneys. SPINRAZA leaves the body (is excreted) through the kidneys. It is important that your kidneys work well while you are taking SPINRAZA.

See the **Serious side effects and what to do about them** table for more information on these and other serious side effects.

Pregnancy: It is not known if SPINRAZA can harm an unborn baby. Therefore, SPINRAZA is not recommended during pregnancy. If you discover that you are pregnant while taking SPINRAZA, tell your healthcare professional **right away**.

Breastfeeding: It is not known if SPINRAZA can pass into breast milk and harm a breastfed baby. Talk to your healthcare professional about other ways to feed your baby during your treatment with SPINRAZA.

Check-ups and testing: Your healthcare professional will do tests before you or your child start receiving SPINRAZA and during treatment if needed. These tests may include:

- blood tests to monitor:
 - the level of platelets in the blood.
 - your or your child’s blood clotting.
- urine tests to monitor the health of your or your child’s kidneys.

Tell your healthcare professional about all the medicines you or your child take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

At this time, there are no known medicines that interact with SPINRAZA. It is unknown if SPINRAZA can be used safely with other medicines that are administered into the spine (intrathecal).

How SPINRAZA is given:

- SPINRAZA is given by injection to the lower back. This injection:
 - is called a lumbar puncture and is done by inserting a needle in the space around the spinal cord (intrathecal). It should not be injected anywhere else, or taken any other way;
 - will be given by a healthcare professional experienced in doing lumbar punctures and will be done in a healthcare setting;
 - will take 1 to 3 minutes.
- You or your child may also be given a medicine to make you relax or sleep during the injection.
- Your healthcare professional will tell you how long you or your child need to keep receiving SPINRAZA. Don’t stop treatment with SPINRAZA unless your healthcare professional tells you to.
- Ask your healthcare professional if you have any questions about how SPINRAZA is given.

Usual dose:

The recommended dose of SPINRAZA is 12 mg. You or your child will receive SPINRAZA based on the schedule below:

- The first 3 doses of SPINRAZA will be administered 14 days apart: on Day 0, Day 14 and Day 28
- The 4th dose will be administered about a month later, for example on Day 63.
- And then once every 4 months.

Overdose:

If you think you, or a person you are caring for, have been given too much SPINRAZA, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you or your child were unable to receive SPINRAZA on the planned date, contact your healthcare professional **right away**. SPINRAZA should be given as soon as possible after a missed dose.

What are possible side effects from using SPINRAZA?

These are not all the possible side effects you may have when receiving SPINRAZA. If you experience any side effects not listed here, tell your healthcare professional.

When SPINRAZA was tested in clinical trials, most side effects seemed to be:

- continued symptoms of the disease (SMA), such as:
 - breathing problems, muscle weakness, joint and bone problems, or digestive problems
 - sinus and/or throat infections, colds
 - lung infections like bronchitis and pneumonia
- side effects of the lumbar puncture:
 - experienced during or within a few days after SPINRAZA is given

The side effects reported that were likely continued symptoms of the disease included:

- Chest infections (such as pneumonia)
 - wheezing, shortness of breath, chest pain, feeling tired, coughing - sometimes with mucus
- Constipation
- Cough
- Curving of the back or spine (scoliosis)
- Diarrhea

- Difficulty breathing or being unable to breathe
 - signs may include rapid or shallow breathing, an increase in heart rate, and a bluish-tinge of the skin, fingertips or lips
 - may be caused by a collapsed lung or part of a lung
- Difficulty swallowing or being unable to swallow
- Ear infection leading to pain or loss of balance
- Feeling nauseous or throwing up
- Fever
- Heart-burn
- Infections of the nose, throat or upper airways
 - blocked, stuffy or runny nose, sneezing and coughing, a sore or scratchy throat and watery or itchy eyes
- Nose bleed (epistaxis)
- Pain
- Permanent shortening of a muscle or joint
- Rash on forearms, legs, feet, hands
- Reduction in growth
- Stiffness of muscles or joints
- Stomach flu
- Yeast / fungus infection in mouth (oral thrush)
 - White patches usually on tongue or inner cheeks

For the side effects that were likely a result of the lumbar puncture, see the **Serious side effects and what to do about them** table (under **Injection site/lumbar puncture reactions**).

Tell your healthcare professional if you or your child experience any of the side effects listed above. Do not treat them yourself. **Contact your healthcare professional if you or your child have any side effects that bother you/your child or that do not go away.**

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNKNOWN FREQUENCY			
Allergic reaction / Angioedema: difficulty swallowing or breathing, wheezing; drop in blood pressure; feeling sick to your stomach and throwing up; hives or rash; swelling of the face, lips, tongue or throat			√

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Aseptic meningitis (inflammation of the protective lining of the brain that is not caused by infection): confusion, fever, nausea, sudden headache or stiffness of your neck, sensitivity to light, vomiting		√	
Blood clotting problems and risk of bleeding: bruising or bleeding for longer than usual if you hurt yourself, fatigue and weakness		√	
Hydrocephalus (buildup of fluid in the brain): increase in head size or bulging soft spot on top of the head (fontanel) in infants, decreased consciousness, persistent nausea, vomiting or headache		√	
Hyponatremia (low sodium in the blood): lethargy, confusion, muscular twitching, achy, stiff or uncoordinated muscles, seizure, coma		√	
Injection site/ lumbar puncture reactions: back pain, dizziness, feeling nauseous or throwing up, headache, pain during the injection, serious infections		√	
Kidney toxicity (damage to the kidneys): back and abdominal pain, change in the colour of urine (pale or dark) decrease in amount of urine produced, pain or discomfort when urinating, swelling of the legs and ankles		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

SPINRAZA will be managed and stored by healthcare professionals. Below are some of the guidelines for storing SPINRAZA:

- Refrigerate at 2°C to 8°C.
- May be stored at up to 30°C for up to 14 days.
- Protect from freezing.
- Protect SPINRAZA from light and keep it in the original carton until it is needed.
- Keep out of reach and sight of children.

If you want more information about SPINRAZA:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.biogen.ca or by calling 1-844-483-3360.

This leaflet was prepared by Biogen Canada Inc.

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