zolgensma®
(onasemnogene abeparvovec-xioi)
suspension for intravenous infusion

Prenatal SMA diagnosis: Take action now

A guide for expectant parents and caregivers

In spinal muscular atrophy (SMA), time is neurons. Treating SMA early is essential to preserving motor neuron cells, which are critical for muscle movement throughout the body, such as sitting, crawling, eating, and breathing. Once motor neuron cells are lost, they cannot be brought back. **ZOLGENSMA® (onasemnogene abeparvovec-xioi)** targets the genetic root cause of SMA with a one-time-only dose to stop SMA progression. ZOLGENSMA is a prescription gene therapy used to treat children less than 2 years old with SMA. Keep reading to find out what you can do now to start the process of getting treatment with ZOLGENSMA and for Important Safety Information about ZOLGENSMA.

Connect

With your support team

- ☐ Once you and your child's doctor decide on ZOLGENSMA as a treatment option, work with the doctor to fill out a Patient Consent Form for the **OneGene Program®** to receive support from a dedicated team that can answer questions about treatment, help with coverage support, and more. Contact the OneGene Program at 855-441-GENE (4363), Monday-Friday (8 AM-8 PM ET). Please be sure to include your contact information in the Patient Consent Form
  - » In addition to our OneGene Program, Novartis Gene Therapies offers personal, one-on-one support from a Family Ambassador who can provide guidance and resources to help you at every step of your treatment journey

Indication

ZOLGENSMA is a prescription gene therapy used to treat children less than 2 years old with spinal muscular atrophy (SMA). ZOLGENSMA is given as a one-time infusion into a vein. ZOLGENSMA was not evaluated in patients with advanced SMA.

Important Safety Information

ZOLGENSMA can increase liver enzyme levels and cause acute serious liver injury or acute liver failure which could result in death. Patients will receive an oral corticosteroid before and after infusion with ZOLGENSMA and will undergo regular blood tests to monitor liver function. Contact the patient's doctor immediately if the patient's skin and/or whites of the eyes appear yellowish, if the patient misses a dose of corticosteroid or vomits it up, or if the patient experiences a decrease in alertness.

Please see additional Important Safety Information on page 3 and the accompanying Full Prescribing Information.

Start

Before your child is born

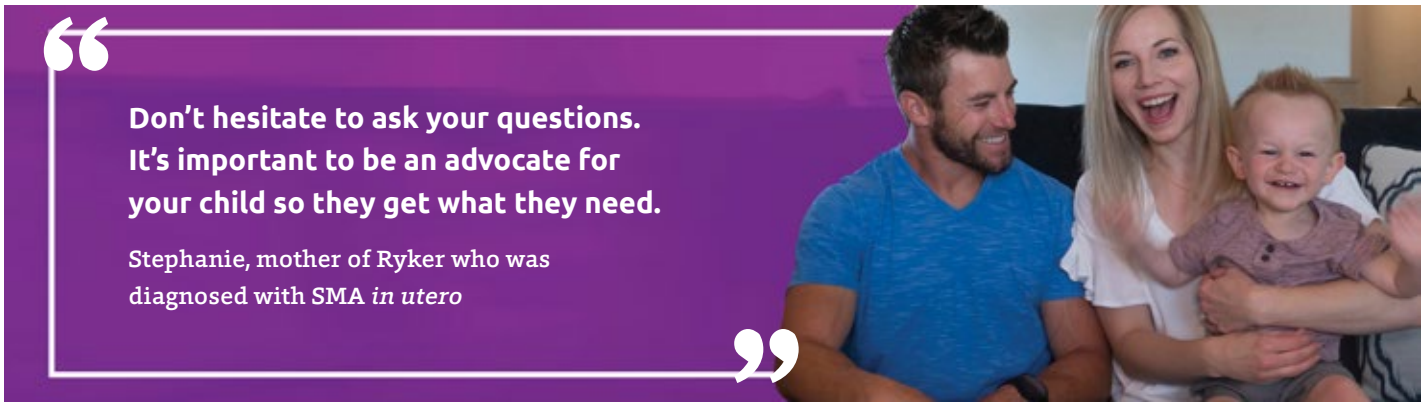
- ☐ As part of your overall birth plan, ask your SMA healthcare team about the **additional lab tests** that may be required to qualify for treatment with ZOLGENSMA® (onasemnogene abeparvovec-xioi). The prescribing doctor will need to request an adeno-associated virus 9, or AAV9, antibody test kit* before your child is born so it's available for testing immediately following birth
- ☐ Consider your health insurance options for treatment. Contact your company's benefits center or human resources department before your child's birth to ask about plan options

*The AAV9 antibody test kit is offered through the Novartis Gene Therapies complimentary lab program.

After your child is born

- ☐ Consult with your child's doctor on where the necessary baseline tests and lab tests for **treatment eligibility** should take place, and schedule the appointment as soon as possible following your child's birth
- ☐ Consider the following suggestions to help speed up the insurance coverage process and approval of ZOLGENSMA:
  - » Insurance policies require a child to be born before providing coverage. On the day your child is born, request that he or she be added to your health insurance plan and contact your employer to confirm coverage. The birth of a child is considered a qualifying event, meaning you are granted a special enrollment period to do this
  - » Due to your child's complex medical diagnosis, you may want to request a case manager from the insurance company or Medicaid for your child

Remember to ask questions, advocate for your child at every step, and trust your instincts!



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Indication and Important Safety Information

What is ZOLGENSMA?

ZOLGENSMA® (onasemnogene abeparvovec-xioi) is a prescription gene therapy used to treat children less than 2 years old with spinal muscular atrophy (SMA). ZOLGENSMA is given as a one-time infusion into a vein. ZOLGENSMA was not evaluated in patients with advanced SMA.

What is the most important information I should know about ZOLGENSMA?

- ZOLGENSMA can increase liver enzyme levels and cause acute serious liver injury or acute liver failure which could result in death.
- Patients will receive an oral corticosteroid before and after infusion with ZOLGENSMA and will undergo regular blood tests to monitor liver function.
- Contact the patient's doctor immediately if the patient's skin and/or whites of the eyes appear yellowish, if the patient misses a dose of corticosteroid or vomits it up, or if the patient experiences a decrease in alertness.

What should I watch for before and after infusion with ZOLGENSMA?

- Infections before or after ZOLGENSMA infusion can lead to more serious complications. Caregivers and close contacts with the patient should follow infection prevention procedures. Contact the patient's doctor immediately if the patient experiences any signs of a possible infection such as coughing, wheezing, sneezing, runny nose, sore throat, or fever.
- Decreased platelet counts could occur following infusion with ZOLGENSMA. Seek immediate medical attention if the patient experiences unexpected bleeding or bruising.
- Thrombotic microangiopathy (TMA) has been reported to generally occur within the first two weeks after ZOLGENSMA infusion. Seek immediate medical attention if the patient experiences any signs or symptoms of TMA, such as unexpected bruising or bleeding, seizures, or decreased urine output.
- There is a theoretical risk of tumor development with gene therapies such as ZOLGENSMA. Contact the patient's doctor and Novartis Gene Therapies, Inc. (1-833-828-3947) if a tumor develops.

What do I need to know about vaccinations and ZOLGENSMA?

- Talk with the patient's doctor to decide if adjustments to the vaccination schedule are needed to accommodate treatment with a corticosteroid.
- Protection against influenza and respiratory syncytial virus (RSV) is recommended and vaccination status should be up-to-date prior to ZOLGENSMA administration. Please consult the patient's doctor.

Do I need to take precautions with the patient's bodily waste?

Temporarily, small amounts of ZOLGENSMA may be found in the patient's stool. Use good hand hygiene when coming into direct contact with patient body waste for one month after infusion with ZOLGENSMA. Disposable diapers should be sealed in disposable trash bags and thrown out with regular trash.

What are the possible or likely side effects of ZOLGENSMA?

The most common side effects that occurred in patients treated with ZOLGENSMA were elevated liver enzymes and vomiting.

The safety information provided here is not comprehensive. Talk to the patient's doctor about any side effects that bother the patient or that don't go away.

You are encouraged to report suspected side effects by contacting the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch, or Novartis Gene Therapies, Inc. at 1-833-828-3947.

Please see the Full Prescribing Information.

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