



# A CARE PLAN for your child after treatment

## Steps to take after your child's infusion with ZOLGENSMA

### Before you leave the infusion center

**Talk** to your child's doctor about what to expect after treatment

**Confirm** follow-up appointments with your child's doctor. The chart on the right can be filled out with appointment details

Along with the single dose of ZOLGENSMA, there are tests your child will need before and after treatment day. It is important to monitor your child and keep track of these appointments so you can bring up any needs your child may have.

Your child's doctor will work with you to create an appointment schedule as you monitor your child and continue on their ZOLGENSMA journey.\*

Your child needs to be treated with an oral corticosteroid before and after infusion. ZOLGENSMA can increase liver enzyme levels and cause acute serious liver injury or acute liver failure which could result in death.†

**Do not abruptly stop using the corticosteroid.**

\*It is important to note that your child will require follow-up appointments for the first 3 months post-infusion, and may need to be monitored for a longer period of time.

†Monitoring beyond 12 weeks may be required.

	Date	Time	Location
Week 1			
Week 2			
Week 3			
Week 4			
Week 5			
Week 6			
Week 7			
Week 8			
Week 9			
Week 10			
Week 11			
Week 12†			

### When you get home

**Continue** to give your child the corticosteroid as prescribed by their doctor, and notify the doctor if your child misses or vomits a dose

**Monitor** your child. Contact your child's doctor immediately if you notice:

- Any signs of infection, including coughing, wheezing, sneezing, runny nose, sore throat, or fever
- Yellowish appearance of the skin or whites of the eyes
- A decrease in alertness
- Unexpected bruising or bleeding
- Seizures
- Decreased urine output
- Any other symptoms your child's doctor may tell you about

**Call your child's doctor with any non-life-threatening questions or concerns. Call 9-1-1 with any life-threatening concerns.**

### INDICATION

**What is ZOLGENSMA?**

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.

**Please see the Indication and Important Safety Information on the next page and the accompanying Full Prescribing Information.**

## 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, during, 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. at 1-833-828-3947 if a tumor develops.
- Infusion-related reactions may occur during and after ZOLGENSMA infusion. Seek immediate medical evaluation if signs and symptoms of infusion-related reaction occur which may include rash, hives, vomiting, shortness of breath, respiratory symptoms, and/or changes in heart rate and blood pressure.

### 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](http://www.fda.gov/medwatch), or Novartis Gene Therapies, Inc. at 1-833-828-3947.

Please see the [Full Prescribing Information](#).



Learn more about treating SMA with ZOLGENSMA  
Visit [www.ZOLGENSMA.com](http://www.ZOLGENSMA.com)

