

MEDICATION GUIDE
ELEVIDYS (Ah-LEV-ah-dis)
(delandistrogene moxeparvovec-rokl)
suspension, for intravenous use

What is the most important information that you/your child should know about ELEVIDYS?

- 1. Rapid serious liver injury and rapid liver failure. ELEVIDYS can increase certain liver lab test levels and cause rapid serious liver injury, rapid liver failure, and death.** Complication of blood clots in the blood vessel in the abdomen that helps carry blood from the intestines to the liver has happened. Patients with preexisting liver problems may be at higher risk.
 - You/your child will receive oral corticosteroid medication before and after ELEVIDYS infusion and will need weekly blood tests to monitor liver function for 3 months or longer after treatment.
 - For at least 2 months following ELEVIDYS infusion, stay close to a healthcare facility that your/your child's doctor recommends.
 - Contact your/your child's doctor immediately if your/your child's skin and/or whites of the eyes appear yellowish or if your/your child misses a dose of corticosteroid or vomits it up.
- 2. Serious Infection.** Because you/your child will be taking corticosteroids as part of ELEVIDYS treatment, this may lower the ability of your/your child's immune system to fight infections and make it easier to get an infection. Getting an infection (like a cold, flu, stomach flu, ear infection, chest infection) before or after ELEVIDYS infusion could lead to more serious health problems, including death. Contact your/your child's doctor right away if you notice any signs of infection such as:
 - coughing
 - wheezing
 - sneezing
 - runny nose
 - sore throat
 - fever
 - Vaccinations should be completed at least 4 weeks before starting the corticosteroids that are part of the ELEVIDYS treatment.
 - **ELEVIDYS should not be given if you have/your child has an infection.**
- 3. Inflammation of the heart muscle (Myocarditis).** Serious and life-threatening inflammation of the heart muscle has happened following ELEVIDYS infusion. In individuals who develop inflammation of the heart muscle after receiving ELEVIDYS, they may be at a higher risk of serious complications if they already had a heart condition that has affected how well the heart pumps.

You/Your child will need weekly blood tests for a heart protein that can detect damage to muscle cells in the heart (troponin-I) for the first month after ELEVIDYS infusion. Contact your/your child's doctor right away if you notice:

 - chest pain
 - trouble breathing or shortness of breath
- 4. Infusion-related reactions.** Reactions from the infusion, including serious allergic reactions, may happen during or after ELEVIDYS infusion. Contact your/your child's doctor right away if you notice:
 - fast heart rate
 - fast breathing
 - swollen lips
 - short of breath
 - nostrils widening
 - hives
 - red and blotchy skin
 - itchy or inflamed lips
 - rash
 - vomiting
 - nausea
 - chills
 - fever
- 5. Immune response affecting muscles (Immune-mediated myositis).** Immune response affecting muscles, including serious and life-threatening reactions, has happened in patients about one month after receiving ELEVIDYS infusion. Contact your/your child's doctor right away if you notice:
 - Unexplained increased muscle pain
 - Tenderness
 - Weakness, including trouble swallowing, breathing or speaking

See “**What are the possible side effects of ELEVIDYS?**” for more information about side effects.

What is ELEVIDYS?

ELEVIDYS is a prescription gene therapy used to treat ambulatory individuals at least 4 years old with Duchenne muscular dystrophy (DMD) who have a confirmed mutation in the *DMD* gene.

ELEVIDYS is not recommended for individuals with:

- Preexisting liver problems or liver infection because of the high risk of rapid serious liver injury and rapid liver failure
- Recent vaccination (within 4 weeks of ELEVIDYS treatment)
- Current or recent infections (within 4 weeks of ELEVIDYS treatment)

Who should not take ELEVIDYS?

You/Your child should not receive ELEVIDYS if they have a certain type of genetic mutation, called a deletion, involving any portion of or the entire exon 8 and/or exon 9 in the *DMD* gene.

Before taking ELEVIDYS, tell your child’s doctor about all your child’s medical conditions, including if they have:

- preexisting liver problems
- current or recent infection
- recent vaccinations (within 4 weeks)

How should your child receive ELEVIDYS?

- Before receiving ELEVIDYS, you/your child will need to get blood tests to check:
 - the amount of antibodies to ELEVIDYS
 - liver function
 - platelets, which is a kind of blood cell that helps you stop bleeding
 - heart protein
- Your/Your child’s healthcare provider will give ELEVIDYS into a vein of the arm through an intravenous (IV) line that may last around 1 to 2 hours or longer.
- Your/Your child’s healthcare provider will check on you/your child during and at least 3 hours after the infusion for infusion-related reactions. See “**What is the most important information I should know about ELEVIDYS?**” If an infusion-related reaction occurs during their ELEVIDYS infusion, your/your child’s healthcare provider may decide to give ELEVIDYS more slowly or stop the infusion.

What are the possible side effects of ELEVIDYS?

- **ELEVIDYS can cause serious side effects.** See “**What is the most important information I should know about ELEVIDYS?**”
- **The most common side effects in individuals treated with ELEVIDYS include:**
 - vomiting
 - nausea
 - liver injury
 - fever
 - lower number of platelets, which is a kind of blood cell that helps you stop bleeding
 - higher number of heart protein that can detect damage to muscles cells in the heart (troponin-I)

Tell your/your child’s doctor about any side effects that bother you/your child or that do not go away. These are not all the possible side effects of ELEVIDYS.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

You may also report side effects to Sarepta Therapeutics, Inc. at 1-888-727-3782.

What should you/your child avoid after receiving ELEVIDYS?

- Avoid taking new medications that are known to damage the liver as this may make liver problems worse. **Tell your doctor about all the medicines you/your child takes**, including prescription and over-the counter medicines, vitamins, and herbal supplements.
- Discuss with your/your child’s doctor before receiving a vaccine after ELEVIDYS treatment.
- Avoid missing any dose of corticosteroids. Contact your/your child’s doctor immediately if this happens.

See **“What is the most important information I should know about ELEVIDYS?”**

General information about the safe and effective use of ELEVIDYS.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your/your child’s pharmacist or doctor for information about ELEVIDYS that is written for health professionals.

What are the ingredients in ELEVIDYS?

Active ingredients: delandistrogene moxeparvovec-rokl

Inactive ingredients: sodium chloride, tromethamine hydrochloride, tromethamine, magnesium chloride, poloxamer 188

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This Medication Guide has been approved by the U.S. Food and Drug Administration.

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