

Delandistrogene Moxeparvovec

This information from UpToDate® Lexidrug™ explains what you need to know about this medication, including what it's used for, how to take it, its side effects, and when to call your healthcare provider.

Brand Names: US

Elevidys

Warning

- Severe liver problems have happened with this drug. Some of these were life-threatening or deadly. The risk of liver problems may be higher if your child already has liver problems. Most of the time, this happened within 8 weeks after the dose. Call the doctor right away if your child has any signs of liver problems.
- Your child will need to have liver tests before getting this drug and weekly for at least 3 months after getting the dose.
- Your child will need to stay close to an appropriate healthcare facility for at least 2 months after getting this drug. Talk with your child's doctor.

What is this drug used for?

- It is used to treat Duchenne muscular dystrophy (DMD).

What do I need to tell the doctor BEFORE my child takes this drug?

- If your child is allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell the doctor about the allergy and what signs your child had.
- If your child has an infection, or if your child has had an infection within the past 4 weeks.
- If your child has had a vaccine within the past 4 weeks.
- If your child has liver disease.
- If your child has been tested and you know that your child has a deletion in exon 8 or exon 9 in the DMD gene.
- If your child has been tested and you know that your child has anti-AAV antibodies.
- If your child is pregnant or may be pregnant. This drug is not for use during pregnancy.
- If your child is breast-feeding a baby or plans to breast-feed a baby.

This is not a list of all drugs or health problems that interact with this drug.

Tell the doctor and pharmacist about all of your child's drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe to give this drug with all of your child's other drugs and health problems. Do not start, stop, or change the dose of any drug your child takes without checking with the doctor.

What are some things I need to know or do while my child takes this drug?

- Tell all of your child's health care providers that your child is taking this drug. This includes your child's doctors, nurses, pharmacists, and dentists.
- Have your child's blood work and other lab tests checked as you have been told by the doctor.

- Make sure your child is up to date with all vaccines before treatment with this drug. Talk with your child's doctor to find out when your child needs to get any vaccines before starting this drug.
- A steroid drug like prednisone will be given before and after this drug to help avoid side effects. Tell the doctor if the steroid drug is not used as you have been told.
- This drug taken with a steroid may raise the risk of an infection becoming severe. Some infections have been deadly. Have your child wash hands often. Have your child stay away from people with infections, colds, or flu. Tell the doctor if your child has signs of an infection before starting this drug or after taking it. Some signs of infection may include fever, chills, sore throat, cough, wheezing, sneezing, or runny nose.
- After getting this drug, urine and stools may have this drug in them. You will need to take special care for 1 month after your child gets this drug. Wash your hands well. Put anything that may have your child's urine or stools on it in a sealed bag and throw it away in household waste. If you have questions, talk with your child's doctor.

What are some side effects that I need to call my child's doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your child's doctor or get medical help right away if your child has any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of liver problems like dark urine, tiredness, decreased appetite, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.
- Confusion or other mental changes.

- Any unexplained bruising or bleeding.
- Muscle problems have happened about 1 month after the infusion. Sometimes these have been severe or life-threatening. Tell the doctor right away if your child has any unexplained increase in muscle pain, tenderness, or weakness. This includes trouble swallowing, shortness of breath, or trouble speaking.
- Severe heart problems have been seen within 24 hours to more than 1 year after the infusion. Some of these have been life-threatening. Call your child's doctor right away if your child has chest pain, shortness of breath, or swelling.
- An infusion reaction may happen with this drug. Your child will be watched for a reaction while getting this drug and for at least 3 hours after the infusion is done. Tell your doctor right away if your child has a fast heartbeat, fast breathing, trouble breathing, or nose flaring. Tell the doctor right away if your child has lip swelling or itching, rash or hives, fever, chills, flushing, upset stomach, or throwing up.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your child's doctor or get medical help if any of these side effects or any other side effects bother your child or do not go away:

- Upset stomach or throwing up.
- Mild fever.

These are not all of the side effects that may occur. If you have questions about side effects, call your child's doctor. Call your child's doctor for medical advice about side effects.

You may report side effects to your national health agency.

How is this drug best given?

Give this drug as ordered by your child's doctor. Read all information given to you. Follow all instructions closely.

- It is given as an infusion into a vein over a period of time.

What do I do if my child misses a dose?

- Call your child's doctor to find out what to do.

How do I store and/or throw out this drug?

- If you need to store this drug at home, talk with your child's doctor, nurse, or pharmacist about how to store it.

General drug facts

- If your child's symptoms or health problems do not get better or if they become worse, call your child's doctor.
- Do not share your child's drug with others and do not give anyone else's drug to your child.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your child's doctor, nurse, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

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If you have questions or concerns, contact your healthcare provider. A member of your care team will answer Monday through Friday from 9 a.m. to 5 p.m. Outside those hours, you can leave a message or talk with another MSK provider. There is always a doctor or nurse on call. If you're not sure how to reach your healthcare provider, call 212-639-2000.

For more resources, visit www.mskcc.org/pe to search our virtual library.

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