Memorial Sloan Kettering Cancer Center

PATIENT & CAREGIVER EDUCATION

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 you already have liver problems. Most of the time, this happened within 8 weeks after the dose. Call your doctor right away if you have any signs of liver problems.
- You will need to have liver tests before getting this drug and weekly for at least 3 months after getting the dose.
- You will need to stay close to an appropriate healthcare facility for at least 2 months after getting this drug. Talk with your doctor.

What is this drug used for?

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

What do I need to tell my doctor BEFORE I take this drug?

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.
- If you have an infection, or if you have had an infection within the past 4 weeks.

- If you have had a vaccine within the past 4 weeks.
- If you have liver disease.
- If you have been tested and know that you have a deletion in exon 8 or exon 9 in the DMD gene.
- If you have been tested and know that you have anti-AAV antibodies.
- If you are pregnant or may be pregnant. This drug is not for use during pregnancy.
- If you are breast-feeding or plan to breast-feed.

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

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

What are some things I need to know or do while I take this drug?

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.

- Have your blood work and other lab tests checked as you have been told by your doctor.
- Make sure you are up to date with all your vaccines before treatment with this drug. Talk with your doctor to find out when you need 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. Wash your hands often. Stay away from people with infections, colds, or flu. Tell your doctor if you have 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 getting this drug. Wash your hands well. Put anything that may have your urine or stools on it in a sealed bag and throw it away in household waste. If you have questions, talk with your doctor.

What are some side effects that I need to call my 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 doctor or get medical help right away if you have 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 you have 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 the doctor right away if you have chest pain, shortness of breath, or swelling.

- An infusion reaction may happen with this drug. You 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 you have a fast heartbeat, fast breathing, trouble breathing, or nose flaring. Tell your doctor right away if you have 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 doctor or get medical help if any of these side effects or any other side effects bother you 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 doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

You may report side effects to the FDA at 1- 800-332-1088. You may also report side effects at https://www.fda.gov/medwatch.

How is this drug best taken?

Use this drug as ordered by your 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 I miss a dose?

- Call your 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 doctor, nurse, or pharmacist about how to store it.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- 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 doctor, nurse, pharmacist, or other health care provider.
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- 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.

Consumer Information Use and Disclaimer

This generalized information is a limited summary of diagnosis, treatment, and/or medication information. It is not meant to be comprehensive and should be used as a tool to help the user understand and/or assess potential diagnostic and treatment options. It does NOT include all information about conditions, treatments, medications, side effects, or risks that may apply to a specific patient. It is not intended to be medical advice or a substitute for the

medical advice, diagnosis, or treatment of a health care provider based on the health care provider's examination and assessment of a patient's specific and unique circumstances. Patients must speak with a health care provider for complete information about their health, medical questions, and treatment options, including any risks or benefits regarding use of medications. This information does not endorse any treatments or medications as safe, effective, or approved for treating a specific patient. UpToDate, Inc. and its affiliates disclaim any warranty or liability relating to this information or the use thereof. The use of this information is governed by the Terms of Use, available at https://www.wolterskluwer.com/en/know/clinical-effectiveness-terms.

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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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