

Atidarsagene Autotemcel

This information from Lexicomp® 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

Lenmeldy

What is this drug used for?

- It is used to treat certain children with a health problem called metachromatic leukodystrophy (MLD).
- This drug is used as part of a treatment plan. Be sure you know about the warnings, benefits, and risks of the other parts of the treatment plan. If you have questions, talk with the doctor.

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 is taking a drug to prevent HIV. Do not give a drug to prevent HIV within 1 month before mobilization.

If your child is pregnant:

- Do not give this drug to your child during pregnancy.

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.
- Treatment with this drug may raise the risk of blood cancer. Blood cancer can happen many years after treatment with this drug. This may be life-threatening or deadly. Your child's blood work and other lab tests will need to be checked on a regular basis for at least 15 years after treatment with this drug. If you have questions, talk with your child's doctor.
- Your child may have more chance of getting infections. Have your child wash hands often. Avoid crowds and people with infections, colds, or flu.
- Your child may bleed more easily. Make sure your child is careful and avoids injury. Be sure your child has a soft toothbrush.
- Your child will need to have tests for certain viruses (like hepatitis and HIV) as the doctor has told you.
- If your child needs to be tested for HIV after getting this drug, talk with the doctor. False test results have happened with some types of HIV tests.
- Be sure your child does not donate blood, organs, tissues, or cells at any time after getting this drug.
- Talk with the doctor before your child gets any vaccines. Some types of

vaccines must not be given for at least 6 weeks before starting this drug, during treatment, and for some time after the last dose.

- This drug may raise the risk of blood clots. In one case, this has been deadly. Tell the doctor if your child has ever had a blood clot or has a raised risk of blood clots.
- Talk with the doctor about how drugs used for conditioning may affect being able to get pregnant or father a child later in life.
- If your child is of childbearing age, a pregnancy test may need to be done before starting this drug to show that your child is NOT pregnant.

If your child is or may be sexually active:

- If your child or your child's partner may become pregnant, birth control must be used while taking this drug and for some time after the last dose. Ask the doctor how long birth control must be used. If your child or your child's partner gets pregnant, call the doctor right away.
- If your child plans to get pregnant or breast-feed a baby after getting this drug, talk with the 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. Rarely, some allergic reactions have been life-threatening.
- Signs of swelling in the brain like behavior changes, feeling confused, trouble thinking, weakness, throwing up, trouble swallowing, or trouble sitting or walking.

- Signs of infection like fever, chills, very bad sore throat, ear or sinus pain, cough, more sputum or change in color of sputum, pain with passing urine, mouth sores, or wound that will not heal.
- Signs of bleeding like throwing up or coughing up blood; vomit that looks like coffee grounds; blood in the urine; black, red, or tarry stools; bleeding from the gums; abnormal vaginal bleeding; bruises without a cause or that get bigger; or bleeding you cannot stop.
- 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.
- Weakness on 1 side of the body, trouble speaking or thinking, change in balance, drooping on one side of the face, or blurred eyesight.
- Call the doctor right away if your child has signs of a blood clot like chest, arm, back, neck, or jaw pain or pressure; coughing up blood; numbness or weakness on 1 side of the body; trouble speaking or thinking; change in balance; change in eyesight; shortness of breath; or swelling, warmth, or pain in the leg or arm.

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:

- Mouth irritation or mouth sores.
- Signs of a common cold.
- Diarrhea, stomach cramps, or throwing up.

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?

- This drug will be given in a health care setting.

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

- This drug will be given in a hospital or doctor's office. You will not store it at home.

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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Last Reviewed Date

2024-03-27

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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.

Atidarsagene Autotemcel - Last updated on March 30, 2024

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