PATIENT & CAREGIVER EDUCATION

Elivaldogene Autotemcel

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

Skysona

Warning

- Blood cancer has happened in people taking this drug. This includes life-threatening cases of myelodysplastic syndrome and leukemia. Cancer has been found more than 9 years after use of this drug. Your child will have blood tests every 3 months during treatment and for at least 15 years after treatment ends. Your child will need to be watched lifelong for cancer. Talk with the doctor if you have questions.

What is this drug used for?

- It is used to slow nerve damage in boys with early, active cerebral adrenoleukodystrophy (CALD).

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.
- If your child is taking a drug to treat or prevent HIV. You may need to stop giving your child these drugs for some time.

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.
- This drug may not work for all people who use it. Talk with the doctor.
- Have your child's blood work and other lab tests checked as you have been told by the doctor.
- High blood pressure has happened with this drug. Have your child's blood pressure checked as you have been told by the doctor.
- 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.
- If your child is not up to date with vaccines, talk with your child's doctor. Your child may need to have some vaccines before treatment with this drug.
- 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.

- This drug may lower the ability of your child's bone marrow to make blood cells that your child's body needs. This can lead to very bad and sometimes deadly bleeding problems or infections. Talk with your child's doctor.
- Your child may have more chance of getting an infection. Some infections have been deadly. Have your child wash hands often. Have your child stay away from 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.
- Be sure your child does not donate blood, organs, tissues, or cells at any time after getting this drug.
- If your child's partner may get pregnant, they must use birth control while taking this drug and for some time after the last dose. Ask the doctor how long they must use birth control. If your child's partner gets pregnant, call the doctor right away.
- If your child is able to get pregnant or is breast-feeding a child, talk with the doctor. This drug is not approved in these patients.

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 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 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 high blood pressure like very bad headache or

dizziness, passing out, or change in eyesight.

- Signs of low potassium levels like muscle pain or weakness, muscle cramps, or a heartbeat that does not feel normal.
- A severe nosebleed or a nosebleed that will not stop.
- A fast heartbeat.
- Swollen gland.
- Feeling very tired or weak.
- Weight loss without trying.
- Seizures.
- Anxiety.
- Blurred eyesight.

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:

- Hair loss.
- Mouth irritation or mouth sores.
- Mouth pain.
- Throat irritation.

- Constipation, diarrhea, stomach pain, upset stomach, throwing up, or decreased appetite.
- Headache.
- Change in skin color.
- Pain and irritation where this drug goes into the body.

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.

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 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.
- Other drugs may be given before this drug to help avoid side effects.

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.
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leaflet. Check with your pharmacist. If you have any questions about this drug, please talk with your 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.

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

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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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