PATIENT & CAREGIVER EDUCATION

Omidubicel

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

Omisirge

Warning

- Infusion reactions have happened with this drug. Infusion reactions may be deadly. Tell your child's doctor if your child has an allergy to dimethyl sulfoxide (DMSO), Dextran 40, gentamicin, albumin, or products made from cows. Tell your child's doctor right away if your child has fever; hives; itching; signs of low blood pressure like dizziness or passing out; swelling of the hands, face, lips, eyes, tongue, or throat; wheezing; or trouble swallowing or breathing during or after the infusion.
- A health problem called graft-vs-host disease (GvHD) has happened with this drug. GvHD may be deadly. Taking drugs to suppress the immune system may help to lower the risk of GvHD. Tell your child's doctor right away if your child has a rash, diarrhea, yellow skin or eyes, chest pain, mouth problems like dry mouth, eye problems like dry eyes, or severe stomach pain.
- A health problem called engraftment syndrome may happen with this drug. This may be deadly. Tell your child's doctor right away if your child has unexplained fever, rash, trouble breathing, or weight gain.
- Sometimes, a stem cell transplant does not work. This can be deadly. Have your child's blood work and other lab tests checked as you have been told by your child's doctor.
- Low blood cell counts have happened after use of this drug to treat severe aplastic anemia. Blood cell counts will be watched before and after the infusion.

What is this drug used for?

- It is used in some people who get a type of stem cell transplant to help the number of white blood cells increase faster and lower the risk of infection.
- It is used to treat aplastic anemia.

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.

This drug may interact with other drugs or health problems.

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.
- You will need to be sure that your child is not dehydrated before getting this drug. Check with the doctor to see if you need to have your child drink extra fluids before getting this drug.
- There is a chance of cancer from the donor cells with this drug, which can be deadly. This includes posttransplant lymphoproliferative disorder (PTLD) and myelodysplastic syndrome (MDS). If you have questions, talk with the doctor.
- This drug is made from umbilical cord blood and may have viruses that may cause disease. Donors are screened to lower the chance of infection. Drugs made from umbilical cord blood may also pass some rare genetic diseases. If you have questions, talk with the doctor.
- Products made from cows are also used when making this drug. These are tested to lower the chance of infection. If you have questions, talk with the doctor.

- If your child is of childbearing age, a pregnancy test will need to be done before starting this drug to make sure your child is not pregnant.

If your child is pregnant or breast-feeding a baby:

- Talk with the doctor if your child is pregnant, becomes pregnant, or is breast-feeding a baby. You will need to talk about the benefits and risks to your child and the baby.

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 kidney problems like unable to pass urine, change in how much urine is passed, blood in the urine, or a big weight gain.
- Signs of fluid and electrolyte problems like mood changes, confusion, muscle pain or weakness, fast or abnormal heartbeat, severe dizziness or passing out, increased thirst, seizures, feeling very tired or weak, decreased appetite, unable to pass urine or change in the amount of urine produced, dry mouth, dry eyes, or severe upset stomach or throwing up.
- Signs of high blood sugar like confusion, feeling sleepy, unusual thirst or hunger, passing urine more often, flushing, fast breathing, or breath that smells like fruit.
- Signs of high or low blood pressure like very bad headache or dizziness, passing out, or change in eyesight.
- 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.

- Small red or purple, flat round spots under the skin.
- Depression.
- Anxiety.
- Shortness of breath.
- Swelling.
- Dark urine or yellow skin or eyes.
- Abnormal heartbeat.
- Call your child's doctor right away if your child has any signs of infection like fever, chills, flu-like signs, severe sore throat, ear or sinus pain, cough, more sputum or change in color of sputum, pain with passing urine, mouth sores, or a wound that will not heal. Some infections have been deadly.

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:

- Feeling dizzy, sleepy, tired, or weak.
- Trouble sleeping.
- Signs of a common cold.
- Muscle weakness.
- Shakiness.
- Mouth irritation.
- Heartburn.
- Weight loss.
- Change in taste.

- Constipation, diarrhea, throwing up, and upset stomach are common with this drug. If these happen, talk with your child's doctor about ways to lower these side effects. Call your child's doctor right away if any of these effects bother your child, do not go away, or are severe.

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.
- Other drugs will be given to help with infusion reactions.

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 healthcare setting. 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.

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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