PATIENT & CAREGIVER EDUCATION

Inotuzumab Ozogamicin

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

Besponsa

Brand Names: Canada

Besponsa

Warning

- Liver problems have happened with this drug. Sometimes, this has been life-threatening or deadly. The chance of liver problems is higher in people who had a stem cell transplant after treatment with this drug. It is also higher in people who have already had liver problems, who have had more treatments with this drug, and in older patients. Tell your child's doctor if your child has ever had liver problems or a stem cell transplant.
- Have blood work checked as you have been told by the doctor. Talk with the doctor.
- Call the doctor right away if your child has signs of liver problems like dark urine, tiredness, decreased appetite, upset stomach, stomach pain, light-colored stools, throwing up, or yellow skin or eyes.
- One study reported a higher rate of death in patients who had a stem cell transplant after getting this drug compared to certain other drugs. If you have questions or concerns, talk with your child's doctor.

What is this drug used for?

- It is used to treat a type of leukemia.

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 any drugs that can cause a certain type of heartbeat that is not normal (prolonged QT interval). There are many drugs that can do this. Ask the doctor or pharmacist if you are not sure.

If your child is breast-feeding a baby:

- Be sure your child does not breast-feed a baby while taking this drug or for 2 months after the last dose.

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 checked and an ECG (to see how your child's heart beats) as you have been told by the doctor.
- This drug may lower the ability of the bone marrow to make blood cells that the body needs. If blood cell counts get very low, this can lead to bleeding problems, infections, or anemia. If you have questions, talk with the doctor.
- Your child may bleed more easily. Make sure your child is careful and avoids injury. Be sure your child has a soft toothbrush. Rarely, some bleeding problems have been deadly.
- 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.
- This drug may affect fertility. Fertility problems may lead to not being able to get pregnant or father a child. If you

have questions, talk with the doctor before your child takes this drug.

- 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 or may be sexually active:

- This drug may cause harm to the unborn baby if your child takes it during pregnancy.
- If your child may become pregnant, have your child use birth control while taking this drug and for 8 months after the last dose. If your child gets pregnant, call the doctor right away.
- If your child's sex partner may become pregnant, have them use birth control while taking this drug and for 5 months after the last dose. If your child's sex partner gets pregnant, call the doctor right away.

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 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.
- Dizziness or passing out.
- Swelling.
- Anxiety.
- A type of abnormal heartbeat (prolonged QT interval) can happen with this drug. Call the doctor right away if your child has a fast heartbeat, a heartbeat that does not feel normal, or if your child passes out.
- This drug may cause a bad and sometimes deadly health problem called tumor lysis syndrome (TLS). Call your child's doctor right away if your child has a fast

heartbeat or a heartbeat that does not feel normal; any passing out; trouble passing urine; muscle weakness or cramps; upset stomach, throwing up, loose stools or not able to eat; or feel sluggish.

- Infusion reactions have happened with this drug. Sometimes, these could be severe or life-threatening. Tell the doctor right away if your child has fever, chills, rash, trouble breathing, or any other bad reaction while getting this drug or within 1 hour after treatment ends.

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 tired or weak.
- Headache.
- Sweating.
- Back, neck, arm, or leg pain.
- Muscle weakness.
- Weight gain.
- Stomach pain.
- Constipation.

- Mouth irritation or mouth sores.
- Diarrhea, throwing up, upset stomach, and decreased appetite 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 get better, 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 with this drug to help avoid side effects.

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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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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