

PATIENT & CAREGIVER EDUCATION

Ravulizumab

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

Ultomiris

Brand Names: Canada

Ultomiris

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Warning

- This drug raises the risk of severe meningococcal infections. Life-threatening and deadly meningococcal infections have happened in people treated with this type of drug. This type of infection can become life-threatening or deadly very fast and can be deadly if not treated early. You will need to get a meningococcal vaccine at least 2 weeks before starting this drug unless your doctor tells you otherwise. If you have had a meningococcal vaccine before, you may need to get another one. Talk with your doctor if you have questions.
- Meningococcal vaccines lower the risk of meningococcal infections but do not prevent all meningococcal infections from happening. Call your doctor right away if you have signs of a meningococcal infection like headache with upset stomach or throwing up, fever, or stiff neck or back; confusion; fever with or without a rash or fast heartbeat; body aches with flu-like signs; or if light bothers your eyes.

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What is this drug used for?

- It is used to treat a blood disease called paroxysmal nocturnal hemoglobinuria (PNH).
- It is used to treat a blood and kidney disease called atypical hemolytic uremic syndrome (aHUS).
- It is used to treat myasthenia gravis.

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

- 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 did not get a meningococcal vaccine.
- If you have a meningococcal infection.
- If you are breast-feeding. Do not breast-feed while you take this drug and for 8 months after your last dose.

On-body Injector:

If you have an allergy to adhesive.

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

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(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? All products:

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- This drug may raise the risk of other severe infections.
 This includes gonorrhea infections in some people.
 Talk to your doctor to see if you have a greater chance of gonorrhea, how to prevent gonorrhea, and if you need to get tested.
- Wash hands often. Stay away from people with infections, colds, or flu.
- Make sure you are up to date with all your vaccines before treatment with this drug.
- Have patient safety card with you at all times and for 8 months after drug is stopped.
- Have your blood work and other lab tests checked as you have been told by your doctor.

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- Some health problems may happen after this drug is stopped. You will need to be watched closely for several weeks to months after you stop this drug. Follow up with your doctor. Call your doctor right away if you have a change in how much urine is passed; dark urine; swelling, warmth, or pain in the leg or arm; chest pain or pressure; coughing up blood; trouble breathing or swallowing; any unexplained bruising or bleeding; seizures; stomach pain; severe dizziness; or passing out. Call your doctor right away if you feel confused, very tired or weak, or have weakness on 1 side of the body, trouble speaking or thinking, change in balance, drooping on 1 side of the face, or change in eyesight. Call your doctor right away if you are not able to get or keep an erection.
- You may need to use birth control to prevent pregnancy while you take this drug and for some time after your last dose. Talk with your doctor to see if you need to use birth control.
- Tell your doctor if you are pregnant or plan on getting pregnant. You will need to talk about the benefits and risks of using this drug while you are pregnant.

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On-body Injector:

- Call the doctor right away if you think that the device may not have worked the right way. Call the doctor right away if the On-body Injector comes off before or during a dose, if it is leaking, or if the sticky part is wet. Call the doctor right away if the light on the On-body Injector flashes red.
- If you have chest pain, trouble breathing, swelling of the face, feel faint, or pass out while using an on-body injector, take it off and get medical help right away.

Vials (for IV infusion):

- If your weight changes, talk with your doctor. The dose of this drug may need to be changed.
- If the patient is a child, use this drug with care. The risk of certain severe infections may be raised in children.

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:

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All products:

- 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 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 a urinary tract infection (UTI) like blood in the urine, burning or pain when passing urine, feeling the need to pass urine often or right away, fever, lower stomach pain, or pelvic pain.
- Signs of high or low 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.
- Swelling in the arms or legs.
- Bruising.
- Swollen gland.

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• Infusion reactions have happened during the infusion. Tell your doctor right away if you have arm or leg pain; back pain; bad taste in your mouth; feeling sleepy; chest pain; trouble breathing; swelling of the face, tongue, or throat; severe dizziness or passing out; or any other bad effects during or within 1 hour after the infusion.

Vials (for IV infusion):

• Pain and irritation where this drug goes into the body.

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:

On-body Injector:

- Pain, redness, swelling, or other reaction where the injection was given.
- Signs of a common cold.
- Headache.
- Diarrhea.

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Vials (for IV infusion):

- Signs of a common cold.
- Nose or throat irritation.
- Headache.
- Constipation, diarrhea, stomach pain, upset stomach, throwing up, or decreased appetite.
- Feeling dizzy, tired, or weak.
- Back, muscle, joint, arm, or leg pain.
- Muscle spasm.
- Anxiety.
- Hair loss.
- Dry skin.

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.

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How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

On-body Injector:

- It is given as a shot into the fatty part of the skin.
- If you will be using this drug at home, your doctor or nurse will teach you how to use it.
- If stored in a refrigerator, let this drug come to room temperature before using it. Leave it at room temperature for at least 45 minutes. Do not heat this drug.
- Do not open until you are ready to use.
- Do not get the device wet.
- Do not shake.
- Do not use this drug if it has been dropped or if it is broken.
- Do not use if the solution is cloudy, leaking, or has particles.
- This drug is colorless to a faint yellow. Do not use if the solution changes color.
- Wash your hands before and after use.
- Give this drug into clean, dry, healthy skin on the

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- belly, upper leg, or upper arm.
- Move the site where you give this drug as you were told by the doctor.
- Do not give into skin within 2 inches (5 cm) of the belly button.
- Do not give into skin that is irritated, tender, bruised, red, scaly, hard, scarred, or has stretch marks.
- Do not give into skin that is tattooed.
- Do not give into a mole.
- Do not put on skin with a lot of hair.
- Do not use this product on an area of skin that folds or bulges.
- Use this drug within 5 minutes after putting the cartridge in the on-body injector. Do not push the start button until the on-body injector is ready to use and is placed on the skin. This button can only be pushed 1 time.
- It may take up to 10 minutes for the injection to finish. Limit physical activity while getting this drug.
 You can do things like walking, reaching, and bending.
- Keep electronic devices like cell phones at least 4 inches away from this product until the injection is

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done.

- Do not rub the site where you give the shot.
- Throw away after using. Do not use the device more than 1 time.
- Throw away needles in a needle/sharp disposal box.

 Do not reuse needles or other items. When the box is full, follow all local rules for getting rid of it. Talk with a doctor or pharmacist if you have any questions.

Vials (for IV infusion):

 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? On-body system:

- Store in a refrigerator. Do not freeze.
- Store in the outer carton to protect from light.
- If needed, this drug can be left out at room temperature for up to 72 hours. Throw away unopened drug if left at room temperature for more than 72 hours.

• Do not put this drug back in the refrigerator after it

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has been stored at room temperature.

Vials (for IV infusion):

• If you need to store this drug at home, talk with your doctor, nurse, or pharmacist about how to store it.

All products:

- 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.

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.
- 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.

• This drug comes with an extra patient fact sheet

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called a Medication Guide. Read it with care. Read it again each time this drug is refilled. If you have any questions about this drug, please talk with the doctor, 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

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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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