

MEDICATION GUIDE

ULTOMIRIS® (ul-toe-meer-is)

(ravulizumab-cwvz)

injection,

for intravenous or subcutaneous use

What is the most important information I should know about ULTOMIRIS?

ULTOMIRIS is a medicine that affects your immune system. ULTOMIRIS can lower the ability of your immune system to fight infections.

- ULTOMIRIS increases your chance of getting serious and life-threatening meningococcal infections. Meningococcal infections may quickly become life-threatening and cause death if not recognized and treated early.
1. You must receive meningococcal vaccines at least 2 weeks before your first dose of ULTOMIRIS if you have not already had this vaccine.
 2. If your healthcare provider decided that urgent treatment with ULTOMIRIS is needed, you should receive meningococcal vaccination as soon as possible.
 3. If you have not been vaccinated for meningococcal infections and ULTOMIRIS therapy must be initiated immediately, you should also receive 2 weeks of antibiotics with your vaccinations.
 4. If you had a meningococcal vaccine in the past, you might need additional vaccination before starting ULTOMIRIS. Your healthcare provider will decide if you need additional meningococcal vaccination.
 5. Meningococcal vaccines reduce the risk of meningococcal infection but do not prevent all meningococcal infections. Call your healthcare provider or get emergency medical care right away if you get any of these signs and symptoms of a meningococcal infection:
 - headache with nausea or vomiting
 - headache with a stiff neck or stiff back
 - fever and a rash
 - muscle aches with flu-like symptoms
 - headache and fever
 - fever
 - confusion
 - eyes sensitive to light

Your healthcare provider will give you a Patient Safety Card about the risk of meningococcal infection. Carry it with you at all times during treatment and for 8 months after your last ULTOMIRIS dose. Your risk of meningococcal infection may continue for several months after your last dose of ULTOMIRIS. It is important to show this card to any healthcare provider or nurse who treats you. This will help them diagnose and treat you quickly.

ULTOMIRIS is only available through a program called the ULTOMIRIS REMS. Before you can receive ULTOMIRIS, your healthcare provider must:

- enroll in the ULTOMIRIS REMS program.
- counsel you about the risk of meningococcal infection.
- give you information about the symptoms of meningococcal infection.
- give you a **Patient Safety Card** about your risk of meningococcal infection, as discussed above.
- make sure that you are vaccinated with a meningococcal vaccine, and if needed, get revaccinated with the meningococcal vaccine. Ask your healthcare provider if you are not sure if you need to be revaccinated.

ULTOMIRIS may also increase the risk of other types of serious infections.

- People who take ULTOMIRIS may have an increased risk of getting infections caused by *Streptococcus pneumoniae* and *Haemophilus influenzae*.
- If your child is treated with ULTOMIRIS, make sure that your child receives vaccinations against *Streptococcus pneumoniae* and *Haemophilus influenzae* type b (Hib).
- Certain people may also have an increased risk of gonorrhea infection. Talk to your healthcare provider to find out if you are at risk for gonorrhea infection, about gonorrhea prevention, and about regular testing.

Call your healthcare provider right away if you have any new signs or symptoms of infection.

What is ULTOMIRIS?

ULTOMIRIS is a prescription medicine called a monoclonal antibody. ULTOMIRIS is used to treat:

- adults and children 1 month of age and older with a disease called Paroxysmal Nocturnal Hemoglobinuria (PNH).
- adults and children 1 month of age and older with a disease called atypical Hemolytic Uremic Syndrome (aHUS).
ULTOMIRIS is not used in treating people with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).
- adults with a disease called generalized Myasthenia Gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive.

It is not known if ULTOMIRIS is safe and effective in children younger than 1 month of age.

It is not known if ULTOMIRIS is safe and effective for the treatment of gMG in children.

Subcutaneous administration of ULTOMIRIS has not been evaluated and is not approved for use in children.

Who should not receive ULTOMIRIS?

Do not receive ULTOMIRIS if you:

- have a meningococcal infection.
- have not been vaccinated against meningococcal infection unless your healthcare provider decides that urgent treatment with ULTOMIRIS is needed. See **“What is the most important information I should know about ULTOMIRIS.”**

Before you receive ULTOMIRIS, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection or fever.
- are pregnant or plan to become pregnant. It is not known if ULTOMIRIS will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if ULTOMIRIS passes into your breast milk. You should not breastfeed during treatment and for 8 months after your final dose of ULTOMIRIS.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. ULTOMIRIS and other medicines can affect each other causing side effects.

Know the medicines you take and the vaccines you receive. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I receive ULTOMIRIS?

- Your healthcare provider will decide how long you need to receive ULTOMIRIS for your PNH, your aHUS, or your gMG.

Adults with PNH, aHUS, or gMG when administered intravenously (by vein)

- You will be given intravenous ULTOMIRIS infusion by a healthcare provider through a needle placed in a vein
- You will usually receive:
 - a starting dose of intravenous ULTOMIRIS infusion by your healthcare provider, **and then**
 - 2 weeks later, you will start to receive an infusion of ULTOMIRIS every 8 weeks.

Children 1 month of age and older with PNH or aHUS when administered intravenously (by vein)

Your child will be given intravenous ULTOMIRIS infusion by a healthcare provider through a needle placed in a vein

- Your child will usually receive:
 - a starting dose of intravenous ULTOMIRIS infusion by your healthcare provider, **and then**
 - your healthcare provider will decide how often your child will receive their intravenous ULTOMIRIS infusion, either every 4 weeks or every 8 weeks, depending on their weight, starting 2 weeks after the starting dose.

Adults with PNH or aHUS when administered subcutaneously (under your skin)

- You or your caregiver will administer subcutaneous ULTOMIRIS under your skin through an on-body injector.
- Use ULTOMIRIS exactly as your healthcare provider tells you to.
- **Read the Instructions for Use that comes with subcutaneous ULTOMIRIS for instructions about the right way to prepare and give your subcutaneous ULTOMIRIS injections through an on-body injector.**
- If your healthcare provider decides that you or a caregiver can give your injections of subcutaneous ULTOMIRIS, you or your caregiver should receive training on the right way to prepare and inject subcutaneous ULTOMIRIS. It is important that you receive training from your healthcare provider on how to inject subcutaneous ULTOMIRIS before giving an injection.
- You will need 2 on-body delivery systems (each containing 1 on-body injector and 1 prefilled cartridge) for a full subcutaneous ULTOMIRIS dose, and each injection will take about 10 minutes.
- You or your caregiver can administer the injections at the same time or 1 after the other into your stomach (abdomen), thigh, or upper arm.
- **If you are not currently being treated with intravenous ULTOMIRIS or SOLIRIS, you will usually receive:**
 - a starting dose of intravenous ULTOMIRIS infusion by your healthcare provider, and then
 - 2 weeks later, you or your caregiver will start to administer maintenance doses of subcutaneous ULTOMIRIS weekly.

If you are changing treatment between ULTOMIRIS administered intravenously, ULTOMIRIS administered subcutaneously, or SOLIRIS:

- **From intravenous ULTOMIRIS to subcutaneous ULTOMIRIS**, you should receive your first dose of subcutaneous ULTOMIRIS 8 weeks after your last dose of intravenous ULTOMIRIS. No intravenous ULTOMIRIS starting dose is needed.

- **From subcutaneous ULTOMIRIS to intravenous ULTOMIRIS**, you should receive your first dose of intravenous ULTOMIRIS 1 week after your last dose of subcutaneous ULTOMIRIS.
- **From SOLIRIS to intravenous ULTOMIRIS**, you should receive your starting dose of intravenous ULTOMIRIS at time of your next scheduled dose of SOLIRIS.
- **From SOLIRIS to subcutaneous ULTOMIRIS**, you should receive your starting dose of intravenous ULTOMIRIS at time of your next scheduled dose of SOLIRIS, and then your first dose of subcutaneous ULTOMIRIS 2 weeks after your starting dose of intravenous ULTOMIRIS.
- After each administration, you should monitor for allergic and infusion reactions for at least 1 hour. See **“What are the possible side effects of ULTOMIRIS?”**
- If you have PNH and you stop receiving ULTOMIRIS, your healthcare provider will need to monitor you closely for at least 16 weeks after you stop ULTOMIRIS. Stopping ULTOMIRIS may cause breakdown of your red blood cells due to PNH.

Symptoms or problems that can happen due to red blood cell breakdown include:

- drop in your red blood cell count
 - tiredness
 - blood in your urine
 - stomach-area (abdomen) pain
 - shortness of breath
 - blood clots
 - trouble swallowing
 - erectile dysfunction (ED) in males
- If you have aHUS, your healthcare provider will need to monitor you closely for at least 12 months after stopping treatment for signs of worsening aHUS or problems related to a type of abnormal clotting and breakdown of your red blood cells called thrombotic microangiopathy (TMA).

Symptoms or problems that can happen with TMA may include:

- confusion or loss of consciousness
- seizures
- chest pain (angina)
- difficulty breathing
- blood clots or stroke

If you miss an ULTOMIRIS intravenous or subcutaneous dose, or administer a partial subcutaneous dose of ULTOMIRIS, call your healthcare provider right away.

What are the possible side effects of ULTOMIRIS?

ULTOMIRIS can cause serious side effects including: See **“What is the most important information I should know about ULTOMIRIS?”**

- **Infusion-related reactions.** Infusion-related reactions may happen during your ULTOMIRIS intravenous or subcutaneous treatment. Symptoms of an infusion-related reaction with ULTOMIRIS may include lower back pain, tiredness, feeling faint, discomfort in your arms or legs, bad taste, or drowsiness. Stop treatment of ULTOMIRIS and tell your healthcare provider right away if you develop these symptoms, or any other symptoms during your ULTOMIRIS infusion that may mean you are having a serious infusion reaction, including:
 - chest pain
 - trouble breathing or shortness of breath
 - swelling of your face, tongue, or throat
 - feel faint or pass out
- **Allergic reactions to acrylic adhesive.** Allergic reactions to the acrylic adhesive may happen with your subcutaneous ULTOMIRIS treatment. If you have an allergic reaction during the delivery of subcutaneous ULTOMIRIS, remove the on-body injector and get medical help right away. Your healthcare provider may treat you with medicines to help prevent or treat allergic reaction symptoms as needed.

The most common side effects of ULTOMIRIS in people treated for PNH are:

- upper respiratory tract infection
- local injection site reactions
- headache
- diarrhea

The most common side effects of ULTOMIRIS in people treated for aHUS are:

- upper respiratory tract infection
- diarrhea
- nausea
- vomiting
- headache
- high blood pressure
- fever

The most common side effects of ULTOMIRIS in people with gMG are:

- diarrhea
- upper respiratory tract infections

Tell your healthcare provider about any side effect that bothers you or that does not go away.

These are not all of the possible side effects of ULTOMIRIS.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of ULTOMIRIS.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or healthcare provider for information about ULTOMIRIS that is written for health professionals.

What are the ingredients in ULTOMIRIS?

Active ingredient: ravulizumab-cwvz.

Inactive ingredients:

Intravenous:

ULTOMIRIS 100 mg/mL: L-arginine, polysorbate 80 (vegetable origin), sodium phosphate dibasic, sodium phosphate monobasic, sucrose and Water for Injection.

ULTOMIRIS 10 mg/mL: polysorbate 80 (vegetable origin), sodium chloride, sodium phosphate dibasic, sodium phosphate monobasic and Water for Injection.

Subcutaneous:

ULTOMIRIS 70 mg/mL: L-arginine, polysorbate 80 (vegetable origin), sodium phosphate dibasic, sodium phosphate monobasic, sucrose, and Water for Injection.

Manufactured by Alexion Pharmaceuticals, Inc., 121 Seaport Boulevard, Boston, MA 02210 USA.

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For more information, go to www.ULTOMIRIS.com or call: 1-888-765-4747.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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