

MEDICATION GUIDE
ULTOMIRIS® (ul-toe-meer-is)
(ravulizumab-cwvz)
injection, for intravenous 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 doctor decided that urgent treatment with ULTOMIRIS is needed, you should receive meningococcal vaccination as soon as possible.
 3. If you have not been vaccinated 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 doctor 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 doctor 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 doctor 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 doctor 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 doctor 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

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*.
- Certain people may also have an increased risk of gonorrhea infection. Talk to your doctor to find out if you are at risk for gonorrhea infection, about gonorrhea prevention, and regular testing.

Call your doctor 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 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).

It is not known if ULTOMIRIS is safe and effective in children with PNH.

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

Who should not receive ULTOMIRIS?

Do not receive ULTOMIRIS if you:

- have a meningococcal infection
- have not been vaccinated against meningococcal infection unless your doctor 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 doctor 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 doctor 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 doctor and pharmacist when you get a new medicine.

How should I receive ULTOMIRIS?

- ULTOMIRIS is given through a vein by intravenous (I.V.) infusion usually over about 2 hours in adults and up to 4 hours in children.

If you are an adult with PNH or aHUS, you will usually receive:

- a starting dose of ULTOMIRIS as an infusion by your doctor, 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 aHUS will usually receive:

- a starting dose of ULTOMIRIS as an infusion by your doctor, and then
- your doctor will decide how often your child will receive ULTOMIRIS, either every 4 weeks or every 8 weeks, depending on their weight, starting 2 weeks after the starting dose.

Your doctor will decide how long you need to take ULTOMIRIS for your aHUS.

- **If you are changing treatment from SOLIRIS to ULTOMIRIS, you should receive your starting dose of ULTOMIRIS 2 weeks after your last dose of SOLIRIS.**
- After each infusion, you should be monitored for at least 1 hour for infusion reactions. See “**What are the possible side effects of ULTOMIRIS?**”
- **If you have PNH and you stop receiving ULTOMIRIS, your doctor 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 doctor 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 infusion, call your doctor 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 reactions.** Infusion reactions may happen during your ULTOMIRIS infusion. Symptoms of an infusion reaction with ULTOMIRIS may include lower back pain, pain with the infusion, feeling faint or discomfort in your arms or legs. Tell your doctor or nurse 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

Your doctor will treat your symptoms as needed.

The most common side effects of ULTOMIRIS in people treated for PNH are upper respiratory infection and headache.

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

- upper respiratory infections
- diarrhea
- nausea
- vomiting
- headache
- high blood pressure
- fever

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

These are not all the possible side effects of ULTOMIRIS. For more information, ask your doctor or pharmacist.

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 doctor for information about ULTOMIRIS that is written for health professionals.

What are the ingredients in ULTOMIRIS?

Active ingredient: ravulizumab-cwvz

Inactive ingredients: polysorbate 80 (vegetable origin), sodium chloride, sodium phosphate dibasic, sodium phosphate monobasic, and Water for Injection

Manufactured by Alexion Pharmaceuticals, Inc., 121 Seaport Boulevard, Boston, MA 02210 USA. U.S. License Number 1743

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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