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 may lower the ability of your immune system to fight infections.

- **ULTOMIRIS increases your chance of getting serious meningococcal infections caused by *Neisseria meningitidis* bacteria**. **Meningococcal infections may quickly become life-threatening or cause death if not recognized and treated early.**
  - You must complete or update your meningococcal vaccine(s) at least 2 weeks before your first dose of ULTOMIRIS.
  - If you have not completed your meningococcal vaccines and ULTOMIRIS must be started right away, you should receive the required vaccine(s) as soon as possible.
  - If you have not been vaccinated and ULTOMIRIS must be started right away, you should also receive antibiotics to take for as long as your healthcare provider tells you.
  - If you had a meningococcal vaccine in the past, you might need additional vaccines before starting ULTOMIRIS. Your healthcare provider will decide if you need additional meningococcal vaccines.
  - Meningococcal vaccines 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 serious meningococcal infection**:
    - fever
    - fever with high heart rate
    - headache and fever
    - confusion
    - muscle aches with flu-like symptoms
    - fever and a rash
    - headache with nausea or vomiting
    - headache with stiff neck or stiff back
    - eyes sensitive to light

Your healthcare provider will give you a Patient Safety Card about the risk of serious meningococcal infection. Carry it with you at all times during treatment and for 8 months after your last dose of ULTOMIRIS. 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 who treats you. This will help them diagnose and treat you quickly.

ULTOMIRIS is only available through a program called the ULTOMIRIS and SOLIRIS Risk Evaluation and Mitigation Strategy (REMS). Before you can receive ULTOMIRIS, your healthcare provider must:

- enroll in the ULTOMIRIS and SOLIRIS REMS program
- counsel you about the risk of serious meningococcal infections
- give you information about the signs and symptoms of serious meningococcal infection
- make sure that you are vaccinated against serious infections caused by meningococcal bacteria and that you receive antibiotics if you need to start ULTOMIRIS right away and you are not up to date on your vaccines
- give you a **Patient Safety Card** about your risk of meningococcal infection, as discussed above

ULTOMIRIS may also increase the risk of other types of serious infections caused by encapsulated bacteria, including *Streptococcus pneumoniae, Haemophilus influenzae,* and *Neisseria gonorrhoeae***.**

- If your child is treated with ULTOMIRIS, your child should receive vaccines against *Streptococcus pneumoniae* and *Haemophilus influenzae type b* (Hib).
- Certain people may be at risk of serious infections with gonorrhea. Talk to your healthcare provider about whether you are at risk for gonorrhea infection, about gonorrhea prevention, and regular testing.

For more information about side effects, see **"What are the possible side effects of ULTOMIRIS?"**

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.
- adults with a disease called Neuromyelitis Optica Spectrum Disorder (NMOSD) who are anti-aquaporin-4 (AQP4) 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 or NMOSD in children.

Who should not receive ULTOMIRIS?

Do not receive ULTOMIRIS if you have a serious meningococcal infection when you are starting ULTOMIRIS treatment.

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.
  - **Pregnancy Registry**: There is a registry for pregnant women who take ULTOMIRIS. The purpose of this registry is to check the health of the pregnant mother and her baby. If you are pregnant or become pregnant while taking ULTOMIRIS, talk to your healthcare provider about how you can join this pregnancy registry or you may contact the registry at 1-833-793-0563 or www.UltomirisPregnancyStudy.com to enroll.
- 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, your gMG, or your NMOSD.

Adults with PNH, aHUS, gMG, or NMOSD 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.

If you are changing treatment from SOLIRIS to ULTOMIRIS, you should receive your starting dose of ULTOMIRIS at time of your next scheduled dose of SOLIRIS.

- After each administration, you should monitor for infusion-related 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 infusion, 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 treatment. Symptoms of an infusion-related reaction with ULTOMIRIS may include lower back pain, stomach (abdominal) pain, muscle spasms, changes in blood pressure, tiredness, feeling faint, shaking chills (rigors), discomfort in your arms or legs, or bad taste. 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-related reaction, including:
  - chest pain
  - trouble breathing or shortness of breath
  - swelling of your face, tongue, or throat
  - feel faint or pass out

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

- upper respiratory tract infection
- headache

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

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

- COVID-19 infection
- headache
- back pain
- urinary tract infection
- joint pain (arthralgia)

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:

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.

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. Revised: 06/2024