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 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.

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 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.
- 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.

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-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 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, abdominal pain, muscle spasms, changes in blood pressure, tiredness, feeling faint, shaking chills (rigors), 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-related 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

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. Do not use ULTOMIRIS for a condition for which it was not prescribed. Do not give ULTOMIRIS to other people, even if they have the same symptoms that you have. It may harm them. 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.

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