ULTOMIRIS® (ravulizumab-cwvz) 100 mg/mL FORMULATION FREQUENTLY ASKED QUESTIONS

Alexion is committed to bringing therapies to patients with rare diseases. Through our work with patients, we know that living with a complement-mediated rare disease involves a lot of time for disease management and care. **We recognize how important it is that we keep our patients up to date on any and all changes to our treatments, so we are making every effort to provide this information to you as quickly as possible.**

The following Frequently Asked Questions may not answer all of your questions, so for any additional information, please reach out to one of our OneSource™ Case Managers at 1-888-765-4747.

INDICATIONS

What is ULTOMIRIS?

ULTOMIRIS is a prescription medicine 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.

Please see Important Safety Information on pages 2-4, full Prescribing Information, and Medication Guide for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening meningococcal infections/sepsis.

What is the ULTOMIRIS 100 mg/mL formulation?

ULTOMIRIS (100 mg/mL) is an advanced formulation of ULTOMIRIS that reduces the average annual infusion time by approximately 60% compared to the current formulation and Soliris® (eculizumab). ULTOMIRIS (100 mg/mL) continues to be dosed **every 8 weeks for adults with PNH or aHUS and every 4 weeks for children with aHUS** 1 month of age and older (depending on body weight), following 2 weeks after a starting dose is administered. The ULTOMIRIS 100 mg/mL formulation will be offered in a 300 mg/3 mL vial and a 1,100 mg/11 mL vial.

How does the safety and efficacy of the 100 mg/mL formulation of ULTOMIRIS compare to the original formulation?

The 100 mg/mL formulation of ULTOMIRIS works in the same place in the complement system as the original formulation, meaning it provides safety and efficacy consistent with the original ULTOMIRIS treatment.

Will the original formulation of ULTOMIRIS continue to be available?

ULTOMIRIS (100 mg/mL) will replace the original formulation in 2021, with a transition period of approximately 9 months following FDA approval. Therefore, all existing patients will eventually transition to the 100 mg/mL formulation. During the transition period, our priority is to ensure that patients who are currently prescribed ULTOMIRIS can access the 100 mg/mL formulation and experience a seamless transition without interruption to their infusion schedule. OneSource Case Managers will be available to provide continued support and answer any questions regarding the transition.

What if I have difficulty transitioning to ULTOMIRIS (100 mg/mL), will I have to transition back to Soliris?

Switching from ULTOMIRIS (100 mg/mL) back to the original formulation of ULTOMIRIS has not been studied; however, both formulations work in the same place in the complement system and showed consistent safety and efficacy results in clinical studies.

Your OneSource Case Manager can help you and your healthcare professional make a plan for transitioning to the 100 mg/mL formulation. Switching back to Soliris is an option you can discuss with your healthcare professional.

How does the price compare to the original formulation of ULTOMIRIS? Will my insurance company cover it?

Per infusion, the price of the ULTOMIRIS 100 mg/mL formulation is consistent with the price of the original formulation. The cost of the medicine per infusion depends on the weight-based dose prescribed for you.

Commercial insurance coverage varies from plan to plan. We encourage you to contact your OneSource Case Manager to learn more about your individual insurance plan and specific out-of-pocket costs.

ONESOURCE®
Personalized Patient Support from Alexion

Call 1-888-765-4747, email OneSource@Alexion.com or visit www.AlexionOneSource.com

IMPORTANT SAFETY INFORMATION & INDICATIONS for ULTOMIRIS® (ravulizumab-cwvz)

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

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

- ULTOMIRIS increases your chance of getting serious and life-threatening meningococcal infections that 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 are not vaccinated.
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. Your doctor will decide if you need additional vaccination.
5. Meningococcal vaccines reduce 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 and fever, headache with a stiff neck or stiff back, fever, fever and a rash, confusion, muscle aches with flu-like symptoms and eyes sensitive to light.

IMPORTANT SAFETY INFORMATION & INDICATIONS for ULTOMIRIS® (ravulizumab-cwvz) (continued)

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. It is important to show this card to any doctor or nurse to 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 and a **Patient Safety Card** about the symptoms and your risk of meningococcal infection (as discussed above); and make sure that you are vaccinated with a meningococcal vaccine, and if needed, get revaccinated with the meningococcal vaccine. Ask your doctor if you are not sure if you need to be revaccinated.

ULTOMIRIS may also increase the risk of other types of serious infections. Make sure your child receives vaccinations against *Streptococcus pneumoniae* and *Haemophilis influenzae* type b (Hib) if treated with ULTOMIRIS. Call your doctor right away if you have any new signs or symptoms of infection.

Who should not receive ULTOMIRIS?
Do not receive ULTOMIRIS if you have a meningococcal infection or have not been vaccinated against meningococcal infection unless your doctor decides that urgent treatment with ULTOMIRIS is needed.

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, and are breastfeeding or plan to breastfeed. It is not known if ULTOMIRIS will harm your unborn baby or if it 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 vaccines you receive and medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements which could affect your treatment.

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, and 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 and blood clots or stroke.

What are the possible side effects of ULTOMIRIS?
ULTOMIRIS can cause serious side effects including infusion-related reactions. Symptoms of an infusion-related 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, and feel faint or pass out.

IMPORTANT SAFETY INFORMATION & INDICATIONS for ULTOMIRIS® (ravulizumab-cwvz) (continued)

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 infection, diarrhea, nausea, vomiting, headache, high blood pressure and 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 right away if you miss an ULTOMIRIS infusion or for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.