ALEXION
AstraZeneca Rare Disease

A GUIDE TO MENINGOCOCCAL VACCINATIONS

For Patients Treated With Alexion Complement Inhibitors

ONESOURCE
Personalized Patient Support from Alexion

ULTOMIRIS
(ravulizumab-cwvz)
Injection for Intravenous use
300 mg/3 mL vial

WHY SHOULD I BE VACCINATED?

Receiving treatment with a type of medicine called a complement inhibitor is a risk factor for serious meningococcal infections.

The complement system is an important part of the body's defense against *Neisseria meningitidis*, a type of bacteria that can cause meningococcal infections, which may quickly become life-threatening or cause death if not recognized and treated early. But complement inhibitors suppress the complement system. That makes people taking this type of medicine more susceptible to meningococcal infections.[1-4]

That's why receiving meningococcal vaccinations is an important step in receiving the treatment you need.[3,4]

WHERE CAN I GET VACCINATED?

Sign up at AlexionOneSource.com or call 1.888.765.4747 to get vaccination support from OneSource™, a free and personalized patient support program offered by Alexion.

OneSource can help you locate places to receive your vaccine:

- ✓ Your treating physician or family doctor's office
- ✓ A pharmacy near you
- ✓ The same place you get your infusion
- ✓ Your local health department

WHAT DO I NEED TO KNOW ABOUT THE VACCINATION SCHEDULE?

You must **complete or update** your meningococcal vaccine(s) at least **2 weeks before** your first infusion with a complement inhibitor.[3-4]

There are two types of meningococcal vaccines available in the United States, MenACWY and MenB, which protect against different types of bacteria that cause meningitis.[5] The Advisory Committee on Immunization Practices (ACIP) recommends that adults and children over 10 years old at increased risk **receive both types** of meningococcal vaccines (MenACWY and MenB).[1]

If you have not been vaccinated and treatment must be started right away, you should also receive antibiotics to take for as long as your healthcare provider tells you.

VACCINE	PRIMARY VACCINATION	BOOSTER VACCINATION
MenACWY (Menveo, MenQuadfi)[6]	**2 doses** at least 8 weeks apart	1 dose every 5 years if risk remains
+		
MenB-4C (Bexsero)[6]	**2 doses** at least 1 month apart	1 dose 1 year following completion of primary series and every 2 to 3 years if risk remains
OR		
MenB-FHbp (Trumenba)[6]	**3 doses** 0, 1-2, and 6 months apart*	1 dose 1 year following completion of primary series and every 2 to 3 years if risk remains

*For MenB-FHbp, if dose 2 was administered at least 6 months after dose 1, dose 3 is not needed.

For information on the vaccine schedule for children 10 years old or younger, please contact the treating physician.

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For Patients Treated With Alexion Complement Inhibitors

ONESOURCE
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SOLIRIS® (eculizumab) Injection for Intravenous Use 300 mg/30 mL vial

SUPPORT AT EVERY STEP OF YOUR JOURNEY

OneSource™, a free and personalized patient support program from Alexion, is designed to support your specific needs.

OneSource can help you find a place to get vaccinated, assist with navigating your insurance plan or other resources for covering the vaccination costs, and give you useful tools and information about meningococcal vaccinations.

CALL: 1.888.765.4747

VISIT: AlexionOneSource.com

Scan the QR code above with the camera on your mobile device to access and save the OneSource website and contact information.

To learn more, ask OneSource about a Patient Education Manager (PEM) in your area. The local PEM is available to meet with you one-on-one, virtually or in person, or connect with you at local educational sessions and events.

STAY ON TOP OF YOUR VACCINATIONS

Stay up to date
Enroll in OneSource. A dedicated support team is here to provide information about the most up-to-date ACIP recommendations for meningococcal vaccinations, help with vaccination or treatment logistics, and ongoing support.

Keep track
Call OneSource and ask for a free Meningococcal Vaccination Card. Tracking your vaccines will help you understand which vaccines you may still need and allow you to share your vaccination history with your healthcare team.

Carry a Safety Card
Ask OneSource or your doctor for a Safety Card about your meningococcal infection risk. Fill it out and always carry it with you. Show the card to any doctor or nurse who treats you. This will help them diagnose and treat you quickly.

QUESTIONS YOU MAY ASK YOUR DOCTOR

- How and where can I get vaccinated?
- Who will provide me with a vaccination prescription?
- What are my next steps for getting vaccinated?
- What type of meningococcal vaccines will I receive?
- What do I need if I was vaccinated in the past?
- Do I need boosters before switching Alexion therapies?

References:

1. Mbaeyi SA, Bozio CH, Duffy J, et al. Meningococcal Vaccination: Recommendations of the Advisory Committee on Immunization Practices, United States, 2020. *MMWR Recomm Rep*. 2020;69(9):1-41.
2. Uria JM, Zhang Q, Li Y, et al. A generic mechanism in Neisseria meningitidis for enhanced resistance against bactericidal antibodies. *J Exp Med*. 2008;205(6):1423-1434.
3. ULTOMIRIS. Prescribing Information. Alexion Pharmaceuticals, Inc.
4. SOLIRIS. Prescribing Information. Alexion Pharmaceuticals, Inc.
5. Centers for Disease Control and Prevention. Meningococcal vaccination: what everyone should know. Updated October 12, 2021. Accessed February 28, 2023. https://www.cdc.gov/vaccines/vpd/mening/public/index.html
6. Centers for Disease Control and Prevention. Recommended adult immunization schedules 2022. Updated February 17, 2022. Accessed January 23, 2023. https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf

Please see additional Important Safety Information on page 4, see accompanying full Prescribing Information, scan QR Code, or visit www.soliris.net/PI for SOLIRIS, including Boxed WARNING regarding serious meningococcal infections.

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INDICATIONS & IMPORTANT SAFETY INFORMATION for ULTOMIRIS

INDICATIONS

What is ULTOMIRIS?

ULTOMIRIS is a prescription medicine 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.

IMPORTANT SAFETY INFORMATION

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

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

- **ULTOMIRIS increases your chance of getting serious meningococcal infections that may quickly become life-threatening or cause death if not recognized and treated early.**

1. You must complete or update meningococcal vaccine(s) at least 2 weeks before your first dose of ULTOMIRIS.
2. 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.
3. If you have not been vaccinated and ULTOMIRIS must be started right away, you should also receive antibiotics for as long as your healthcare provider tells you.
4. 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.
5. 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 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 a stiff neck or stiff back, or 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 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 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 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 are not up to date on your vaccines; give you a **Patient Safety Card** about your risk of meningococcal infection.

ULTOMIRIS may also increase the risk of other types of serious infections, including *Streptococcus pneumoniae, Haemophilus influenzae,* and *Neisseria gonorrhoeae*. Your child should receive vaccines against *Streptococcus pneumoniae* and *Haemophilus influenzae* type b (Hib) if treated with ULTOMIRIS. Certain people may be at risk of serious infections with gonorrhea.

Who should not receive ULTOMIRIS?

Do not receive ULTOMIRIS if you have a serious meningococcal infection when you are starting 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, 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 healthcare provider 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 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, and 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 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, 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, and feel faint or pass out.

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

The most common side effects of ULTOMIRIS in people with gMG are diarrhea and 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, and joint pain (arthralgia).

Tell your healthcare provider 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 healthcare provider or pharmacist. Call your healthcare provider 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.

INDICATIONS & IMPORTANT SAFETY INFORMATION FOR SOLIRIS® (eculizumab)

INDICATIONS

What is SOLIRIS?

SOLIRIS is a prescription medicine used to treat:

- people with paroxysmal nocturnal hemoglobinuria (PNH).
- people with atypical hemolytic uremic syndrome (aHUS). SOLIRIS is not for use in treating people with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).
- adults with 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 SOLIRIS is safe and effective in children with PNH, gMG, or NMOSD

IMPORTANT SAFETY INFORMATION

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

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

- **SOLIRIS increases your chance of getting serious meningococcal infections that may quickly become life-threatening or cause death if not recognized and treated early.**

1. You must complete or update your meningococcal vaccine(s) at least 2 weeks before your first dose of SOLIRIS.
2. If you have not been vaccinated and SOLIRIS must be started right away, you should receive the required vaccine(s) as soon as possible.
3. If you have not been vaccinated and SOLIRIS must be started right away, you should also receive antibiotics for as long as your healthcare provider tells you.
4. If you had a meningococcal vaccine in the past, you might need additional vaccines before starting SOLIRIS. Your healthcare provider will decide if you need additional meningococcal vaccines.
5. 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 rash, headache with nausea or vomiting, headache with a stiff neck or stiff back, or 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 3 months after your last dose of SOLIRIS. Your risk of meningococcal infection may continue for several weeks after your last dose of SOLIRIS. It is important to show this card to any healthcare provider who treats you. This will help them diagnose and treat you quickly.

SOLIRIS is only available through a program called the ULTOMIRIS and SOLIRIS Risk Evaluation and Mitigation Strategy (REMS). Before you can receive SOLIRIS, your healthcare provider must: enroll in the 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 SOLIRIS right away and you are not up to date on your vaccines; give you a **Patient Safety Card** about your risk of meningococcal infection.

SOLIRIS may also increase the risk of other types of serious infections, including *Streptococcus pneumoniae, Haemophilus influenzae,* and *Neisseria gonorrhoeae*. Your child should receive vaccines against *Streptococcus pneumoniae* and *Haemophilus influenzae* type b (Hib) if treated with SOLIRIS. Certain people may be at risk of serious infections with gonorrhea. Certain fungal infections *(Aspergillus)* may occur if you take SOLIRIS and have a weak immune system or a low white blood cell count.

Who should not receive SOLIRIS?

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

Before you receive SOLIRIS, 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, and are breastfeeding or plan to breastfeed. It is not known if SOLIRIS will harm your unborn baby or if it passes into your breast milk.

Tell your healthcare provider 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, your healthcare provider will need to monitor you closely for at least 8 weeks after stopping SOLIRIS. Stopping treatment with SOLIRIS 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 the number of your red blood cell count, drop in your platelet count, confusion, kidney problems, blood clots, difficulty breathing, and chest pain.

If you have aHUS, your healthcare provider will need to monitor you closely during and for at least 12 weeks after stopping SOLIRIS for signs of worsening aHUS symptoms or problems related to abnormal clotting (thrombotic microangiopathy). Symptoms or problems that can happen with abnormal clotting may include: stroke, confusion, seizure, chest pain (angina), difficulty breathing, kidney problems, swelling in arms or legs, and a drop in your platelet count.

What are the possible side effects of SOLIRIS?

SOLIRIS can cause serious side effects including serious infusion-related reactions. Tell your healthcare provider or nurse right away if you get any of these symptoms during your SOLIRIS infusion: chest pain, trouble breathing or shortness of breath, swelling of your face, tongue, or throat, and feel faint or pass out. If you have an infusion-related reaction to SOLIRIS, your healthcare provider may need to infuse SOLIRIS more slowly, or stop SOLIRIS.

The most common side effects in people with PNH treated with SOLIRIS include: headache, pain or swelling of your nose or throat (nasopharyngitis), back pain, and nausea.

The most common side effects in people with aHUS treated with SOLIRIS include: headache, diarrhea, high blood pressure (hypertension), common cold (upper respiratory infection), stomach-area (abdominal) pain, vomiting, pain or swelling of your nose or throat (nasopharyngitis), low red blood cell count (anemia), cough, swelling of legs or feet (peripheral edema), nausea, urinary tract infections, and fever.

The most common side effects in people with gMG treated with SOLIRIS include: muscle and joint (musculoskeletal) pain.

The most common side effects in people with NMOSD treated with SOLIRIS include: common cold (upper respiratory infection), pain or swelling of your nose or throat (nasopharyngitis), diarrhea, back pain, dizziness, flu like symptoms (influenza) including fever, headache, tiredness, cough, sore throat, and body aches, joint pain (arthralgia), throat irritation (pharyngitis), and bruising (contusion).

Tell your healthcare provider about any side effect that bothers you or that does not go away. These are not all the possible side effects of SOLIRIS. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please see additional Important Safety Information on page 4, see accompanying full Prescribing Information, scan QR Code, or visit www.soliris.net/PI for SOLIRIS, including Boxed WARNING regarding serious meningococcal infections.

This information is intended for United States residents only.