

INFORMATION ABOUT THIS REQUEST

ULTOMIRIS® (ravulizumab-cwvz) and SOLIRIS® (eculizumab) are available only through a restricted program called the ULTOMIRIS and SOLIRIS REMS (Risk Evaluation and Mitigation Strategy), because of the risk of serious meningococcal infections.

For Patients

Please provide this cover letter and the accompanying Patient Vaccination Information Form to any healthcare provider who is planning to provide you OR has provided you with vaccinations in the past.

For Providers

As a part of the REMS, healthcare providers must assess the patient’s vaccination status against serious infections caused by *Neisseria meningitidis* serogroups A, C, W, Y, and B, prior to starting therapy according to the current Advisory Committee on Immunization Practices (ACIP) recommendations and prescribe antibacterial drug prophylaxis if needed.

This patient has been prescribed ULTOMIRIS or SOLIRIS. Due to the increased risk of serious meningococcal infections, the patient’s vaccination records must be available in order to receive treatment with ULTOMIRIS or SOLIRIS.

Please provide the Date and Trade Name of Primary and/or Adult Vaccinations History for:

- **MenACWY** (Menveo®, Menactra® or MenQuadfi®); **MenB** (Bexsero® or Trumenba®); **MenABCWY** (Penbraya™ or Penmenvly)

For questions about vaccination and vaccination timing, please refer to section 5.1 of the Prescribing Information.

Below are ways to report the requested Vaccination Records to the ULTOMIRIS and SOLIRIS REMS:

- ✓ **FAX** accompanied Patient Vaccination Information Form to 1-866-750-0481
- ✓ **CALL** the ULTOMIRIS and SOLIRIS REMS Program at 1-888-765-4747

We thank you for your attention to this matter.

COMPLETE DIGITAL FORM OR FAX A PRINT COPY TO 1-866-750-0481

This form may be used to collect information to confirm the patient has received the appropriate vaccinations and/or antibacterial drug prophylaxis in accordance with ACIP recommendations to receive ULTOMIRIS and SOLIRIS therapy.

- If this form is not completed and submitted, the ULTOMIRIS and SOLIRIS healthcare setting and pharmacy will need to contact the prescriber or other healthcare provider to confirm the appropriate vaccinations or antibacterial drug prophylaxis prior to dispensing ULTOMIRIS and SOLIRIS.
- Data may be submitted in a different format. The reporter may be contacted if there are questions on information provided.

*Indicates required field

Patient Information					
*Patient Therapy Status	New ULTOMIRIS or SOLIRIS Patient			Existing ULTOMIRIS or SOLIRIS Patient	
*First Name	Middle Initial	*Last Name		*Date of Birth (MM/DD/YYYY)	
*ZIP Code	*Gender	Male	Female	Other	Prefer Not to Provide
*Indication	Paroxysmal Nocturnal Hemoglobinuria (PNH) Atypical Hemolytic Uremic Syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy (TMA) Generalized Myasthenia Gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody-positive Neuromyelitis Optica Spectrum Disorder (NMOSD) who are anti-aquaporin-4 (AQP4) antibody-positive Other (please specify): _____				
Reporter (Healthcare Provider) Information					
*First Name	Middle Initial		*Last Name		
*Phone	Extension		Fax		
*Email	Best Time to Contact		Morning	Afternoon	Evening
Antibacterial Drug Prophylaxis					
*Was the patient administered antibacterial drug prophylaxis?	Yes	No	Unknown	Not Applicable	
	*If Yes, Start Date (MM/DD/YYYY) _____				

Please see Indications & Important Safety Information on pages 3 and 4, and full [Prescribing Information](#) for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections, also available on www.ULTOMIRIS.com.

Please see Indications & Important Safety Information on pages 5 and 6, and full [Prescribing Information](#) for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections, also available on www.SOLIRIS.net.

Patient Information			
*First Name	Middle Initial	*Last Name	*Date of Birth (MM/DD/YYYY)

Primary Meningococcal Vaccination					
MenACWY					
First Dose Information:	Available	Not Available	Administered before ULTOMIRIS or SOLIRIS?		Yes No
Dose Date (MM/DD/YYYY) _____	Date Not Available		BRAND:	Menveo® Menactra® MenQuadfi®	Other/Unknown
Second Dose Information:	Available	Not Available	Administered before ULTOMIRIS or SOLIRIS?		Yes No
Dose Date (MM/DD/YYYY) _____	Date Not Available		BRAND:	Menveo® Menactra® MenQuadfi®	Other/Unknown
MenB					
First Dose Information:	Available	Not Available	Administered before ULTOMIRIS or SOLIRIS?		Yes No
Dose Date (MM/DD/YYYY) _____	Date Not Available		BRAND:	Bexsero® Trumenba®	Other/Unknown
Second Dose Information:	Available	Not Available	Administered before ULTOMIRIS or SOLIRIS?		Yes No
Dose Date (MM/DD/YYYY) _____	Date Not Available		BRAND:	Bexsero® Trumenba®	Other/Unknown
Third Dose Information:	Available	Not Available	Administered before ULTOMIRIS or SOLIRIS?		Yes No
Dose Date (MM/DD/YYYY) _____	Date Not Available		BRAND:	Bexsero® Trumenba®	Other/Unknown
MenABCWY					
First Dose Information:	Available	Not Available/Applicable	Administered before ULTOMIRIS or SOLIRIS?		Yes No
Dose Date (MM/DD/YYYY) _____	Date Not Available		BRAND:	Penbraya™ Penmenvy	Other/Unknown
Second Dose Information:	Available	Not Available <input type="checkbox"/> Not Yet Due	Administered before ULTOMIRIS or SOLIRIS?		Yes No
Dose Date (MM/DD/YYYY) _____	Date Not Available		BRAND:	Penbraya™ Penmenvy	Other/Unknown

Booster/Other Meningococcal Vaccination					
Dose Information:	Available	Not Available	Administered before ULTOMIRIS or SOLIRIS?		Yes No
Dose Date (MM/DD/YYYY) _____	Date Not Available				
BRAND:	Menveo® Menactra®	MenQuadfi® Bexsero®	Trumenba® Penbraya™	Penmenvy	Other/Unknown
Dose Information:	Available	Not Available	Administered before ULTOMIRIS or SOLIRIS?		Yes No
Dose Date (MM/DD/YYYY) _____	Date Not Available				
BRAND:	Menveo® Menactra®	MenQuadfi® Bexsero®	Trumenba® Penbraya™	Penmenvy	Other/Unknown

Please see Indications & Important Safety Information on pages 3 and 4, and full [Prescribing Information](#) for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections, also available on www.ULTOMIRIS.com.

Please see Indications & Important Safety Information on pages 5 and 6, and full [Prescribing Information](#) for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections, also available on www.SOLIRIS.net.

IMPORTANT SAFETY INFORMATION AND INDICATIONS, INCLUDING BOXED WARNING, FOR ULTOMIRIS

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS MENINGOCOCCAL INFECTIONS

ULTOMIRIS, a complement inhibitor, increases the risk of serious infections caused by *Neisseria meningitidis* [see Warnings and Precautions (5.1)] Life-threatening and fatal meningococcal infections have occurred in patients treated with complement inhibitors. These infections may become rapidly life-threatening or fatal if not recognized and treated early.

- **Complete or update vaccination for meningococcal bacteria (for serogroups A, C, W, Y, and B) at least 2 weeks prior to the first dose of ULTOMIRIS, unless the risks of delaying ULTOMIRIS therapy outweigh the risk of developing a serious infection. Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against meningococcal bacteria in patients receiving a complement inhibitor. See Warnings and Precautions (5.1) for additional guidance on the management of the risk of serious infections caused by meningococcal bacteria.**
- **Patients receiving ULTOMIRIS are at increased risk for invasive disease caused by *Neisseria meningitidis*, even if they develop antibodies following vaccination. Monitor patients for early signs and symptoms of serious meningococcal infections and evaluate immediately if infection is suspected.**

Because of the risk of serious meningococcal infections, ULTOMIRIS is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called ULTOMIRIS and SOLIRIS REMS [see Warnings and Precautions (5.2)].

CONTRAINDICATIONS

- Initiation in patients with unresolved serious *Neisseria meningitidis* infection.

WARNINGS AND PRECAUTIONS

Serious Meningococcal Infections

ULTOMIRIS, a complement inhibitor, increases a patient's susceptibility to serious, life-threatening, or fatal infections caused by meningococcal bacteria (septicemia and/or meningitis) in any serogroup, including non-groupable strains. Life-threatening and fatal meningococcal infections have occurred in both vaccinated and unvaccinated patients treated with complement inhibitors.

Revaccinate patients in accordance with ACIP recommendations considering the duration of ULTOMIRIS therapy. Note that ACIP recommends an administration schedule in patients receiving complement inhibitors that differs from the administration schedule in the vaccine prescribing information. If urgent ULTOMIRIS therapy is indicated in a patient who is not up to date with meningococcal vaccines according to ACIP recommendations, provide antibacterial drug prophylaxis and administer meningococcal vaccines as soon as possible. Various durations and regimens of antibacterial drug prophylaxis have been considered, but the optimal durations and drug regimens for prophylaxis and their efficacy have not been studied in unvaccinated or vaccinated patients receiving complement inhibitors, including ULTOMIRIS. The benefits and risks of treatment with ULTOMIRIS, as well as those associated with antibacterial drug prophylaxis in unvaccinated or vaccinated patients, must be considered against the known risks for serious infections caused by *Neisseria meningitidis*.

Vaccination does not eliminate the risk of serious meningococcal infections, despite development of antibodies following vaccination.

Closely monitor patients for early signs and symptoms of meningococcal infection and evaluate patients immediately if infection is suspected. Inform patients of these signs and symptoms and instruct patients to seek immediate medical care if they occur. Promptly treat known infections. Meningococcal infection may become rapidly life-threatening or fatal if not recognized and treated early. Consider interruption of ULTOMIRIS in patients who are undergoing treatment for serious meningococcal infection depending on the risks of interrupting treatment in the disease being treated.

ULTOMIRIS and SOLIRIS REMS

Due to the risk of serious meningococcal infections, ULTOMIRIS is available only through a restricted program called ULTOMIRIS and SOLIRIS REMS.

Prescribers must enroll in the REMS, counsel patients about the risk of serious meningococcal infection, provide patients with the REMS educational materials, assess patient vaccination status for meningococcal vaccines (against serogroups A, C, W, Y, and B) and vaccinate if needed according to current ACIP recommendations two weeks prior to the first dose of ULTOMIRIS. Antibacterial drug prophylaxis must be prescribed if treatment must be started urgently, and the patient is not up to date with both meningococcal vaccines according to current ACIP recommendations at least two weeks prior to the first dose of ULTOMIRIS. Patients must receive counseling about the need to receive meningococcal vaccines and to take antibiotics as directed, signs and symptoms of meningococcal infection, and be instructed to carry the Patient Safety Card at all times during and for 8 months following ULTOMIRIS treatment.

Further information is available at www.UltSolREMS.com or 1-888-765-4747.

Other Infections

Serious infections with *Neisseria* species (other than *Neisseria meningitidis*), including disseminated gonococcal infections, have been reported.

ULTOMIRIS blocks terminal complement activation; therefore, patients may have increased susceptibility to infections, especially with encapsulated bacteria, such as infections caused by *Neisseria meningitidis* but also *Streptococcus pneumoniae*, *Haemophilus influenzae*, and to a lesser extent, *Neisseria gonorrhoeae*. Children treated with ULTOMIRIS may be at increased risk of developing serious infections due to *Streptococcus pneumoniae* and *Haemophilus influenzae* type b (Hib). Administer vaccinations for the prevention of *Streptococcus pneumoniae* and *Haemophilus influenzae* type b (Hib) infections according to ACIP recommendations. Patients receiving ULTOMIRIS are at increased risk for infections due to these organisms, even if they develop antibodies following vaccination.

Monitoring Disease Manifestations after ULTOMIRIS Discontinuation

Treatment Discontinuation for PNH

After discontinuing treatment with ULTOMIRIS, closely monitor for signs and symptoms of hemolysis, identified by elevated LDH along with sudden decrease in PNH clone size or hemoglobin, or re-appearance of symptoms such as fatigue, hemoglobinuria, abdominal pain, shortness of breath (dyspnea), major adverse vascular event (including thrombosis), dysphagia, or erectile dysfunction. Monitor any patient who discontinues ULTOMIRIS for at least 16 weeks to detect hemolysis and other reactions. If signs and symptoms of hemolysis occur after discontinuation, including elevated LDH, consider restarting treatment with ULTOMIRIS.

Treatment Discontinuation for aHUS

ULTOMIRIS treatment of aHUS should be a minimum duration of 6 months. Due to heterogeneous nature of aHUS events and patient-specific risk factors, treatment duration beyond the initial 6 months should be individualized. There are no specific data on ULTOMIRIS discontinuation. After discontinuing treatment with ULTOMIRIS, patients should be monitored for clinical symptoms and laboratory signs of TMA complications for at least 12 months. TMA complications post-discontinuation can be identified if any of the following is observed: Clinical symptoms of TMA include changes in mental status, seizures, angina, dyspnea, thrombosis or increasing blood pressure. In addition, at least two of the following laboratory signs observed concurrently and

results should be confirmed by a second measurement 28 days apart with no interruption: a decrease in platelet count of 25% or more as compared to either baseline or to peak platelet count during ULTOMIRIS treatment; an increase in serum creatinine of 25% or more as compared to baseline or to nadir during ULTOMIRIS treatment; or, an increase in serum LDH of 25% or more as compared to baseline or to nadir during ULTOMIRIS treatment. If TMA complications occur after discontinuation, consider reinitiation of ULTOMIRIS treatment or appropriate organ-specific supportive measures.

Thromboembolic Event Management

The effect of withdrawal of anticoagulant therapy during treatment with ULTOMIRIS has not been established. Treatment should not alter anticoagulant management.

Infusion-Related Reactions

Administration of ULTOMIRIS may result in systemic infusion-related reactions, including anaphylaxis and hypersensitivity reactions. In clinical trials, infusion-related reactions occurred in approximately 1 to 7% of patients, including lower back pain, abdominal pain, muscle spasms, drop or elevation in blood pressure, rigors, limb discomfort, drug hypersensitivity (allergic reaction), and dysgeusia (bad taste). These reactions did not require discontinuation of ULTOMIRIS. If signs of cardiovascular instability or respiratory compromise occur, interrupt ULTOMIRIS and institute appropriate supportive measures.

ADVERSE REACTIONS

Adverse Reactions for PNH

Adverse reactions reported in $\geq 10\%$ or more of patients with PNH were upper respiratory tract infection and headache. Serious adverse reactions were reported in 15 (6.8%) patients receiving ULTOMIRIS. The serious adverse reactions in patients treated with ULTOMIRIS included hyperthermia and pyrexia. No serious adverse reaction was reported in more than 1 patient treated with ULTOMIRIS. One fatal case of sepsis was identified in a patient treated with ULTOMIRIS. In clinical studies, clinically relevant adverse reactions in 1% of adult patients include infusion-related reactions.

Adverse reactions reported in $\geq 10\%$ of pediatric patients treated with ULTOMIRIS who were treatment-naïve vs. Eculizumab-experienced were anemia (20% vs. 25%), abdominal pain (0% vs. 38%), constipation (0% vs. 25%), pyrexia (20% vs. 13%), upper respiratory tract infection (20% vs. 75%), pain in extremity (0% vs. 25%), and headache (20% vs. 25%).

Adverse Reactions for aHUS

Most common adverse reactions in patients with aHUS (incidence $\geq 20\%$) were upper respiratory tract infection, diarrhea, nausea, vomiting, headache, hypertension and pyrexia. Serious adverse reactions were reported in 42 (57%) patients with aHUS receiving ULTOMIRIS. The most frequent serious adverse reactions reported in more than 2 patients (2.7%) treated with ULTOMIRIS were hypertension, pneumonia and abdominal pain.

Adverse reactions reported in $\geq 20\%$ of pediatric patients treated with ULTOMIRIS were diarrhea, constipation, vomiting, pyrexia, upper respiratory tract infection, decreased vitamin D, headache, cough, rash, and hypertension.

Adverse Reactions for gMG

Most common adverse reactions in adult patients with gMG (incidence $\geq 10\%$) were diarrhea and upper respiratory tract infection. Serious adverse reactions were reported in 20 (23%) of patients treated with ULTOMIRIS and in 14 (16%) patients receiving placebo. The most frequent serious adverse reactions were infections reported in at least 8 (9%) patients treated with ULTOMIRIS and in 4 (4%) patients treated with placebo. Of these infections, one fatal case of COVID-19 pneumonia was identified in a patient treated with ULTOMIRIS and one case of infection led to discontinuation of ULTOMIRIS.

Adverse Reactions for NMOSD

Most common adverse reactions in adult patients with NMOSD (incidence $\geq 10\%$) were COVID-19, headache, back pain, arthralgia, and urinary tract infection. Serious adverse reactions were reported in 8 (13.8%) patients with NMOSD receiving ULTOMIRIS.

DRUG INTERACTIONS

Plasma Exchange, Plasmapheresis, and Intravenous Immunoglobulins
Concomitant use of ULTOMIRIS with plasma exchange (PE), plasmapheresis (PP), or intravenous immunoglobulin (IVIg) treatment can reduce serum ravulizumab concentrations and requires a supplemental dose of ULTOMIRIS.

Neonatal Fc Receptor Blockers

Concomitant use of ULTOMIRIS with neonatal Fc receptor (FcRn) blockers (e.g., efgartigimod) may lower systemic exposures and reduce effectiveness of ULTOMIRIS. Closely monitor for reduced effectiveness of ULTOMIRIS.

USE IN SPECIFIC POPULATIONS

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to ULTOMIRIS during pregnancy. Healthcare providers and patients may call [1-833-793-0563](tel:1-833-793-0563) or go to www.UltomirisPregnancyStudy.com to enroll in or to obtain information about the registry.

To report SUSPECTED ADVERSE REACTIONS, contact Alexion Pharmaceuticals, Inc. at 1-844-259-6783 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

INDICATIONS

Paroxysmal Nocturnal Hemoglobinuria (PNH)

ULTOMIRIS is indicated for the treatment of adult and pediatric patients one month of age and older with paroxysmal nocturnal hemoglobinuria (PNH).

Atypical Hemolytic Uremic Syndrome (aHUS)

ULTOMIRIS is indicated for the treatment of adult and pediatric patients one month of age and older with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy (TMA).

Limitation of Use:

ULTOMIRIS is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).

Generalized Myasthenia Gravis (gMG)

ULTOMIRIS is indicated for the treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody-positive.

Neuromyelitis Optica Spectrum Disorder (NMOSD)

ULTOMIRIS is indicated for the treatment of adult patients with neuromyelitis optica spectrum disorder (NMOSD) who are anti-aquaporin-4 (AQP4) antibody positive.

IMPORTANT SAFETY INFORMATION AND INDICATIONS, INCLUDING BOXED WARNING, FOR SOLIRIS

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS MENINGOCOCCAL INFECTIONS

SOLIRIS, a complement inhibitor, increases the risk of serious infections caused by *Neisseria meningitidis* [see Warnings and Precautions (5.1)]. Life-threatening and fatal meningococcal infections have occurred in patients treated with complement inhibitors. These infections may become rapidly life-threatening or fatal if not recognized and treated early.

- **Complete or update vaccination for meningococcal bacteria (for serogroups A, C, W, Y, and B) at least 2 weeks prior to the first dose of SOLIRIS, unless the risks of delaying SOLIRIS therapy outweigh the risk of developing a serious infection. Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against meningococcal bacteria in patients receiving a complement inhibitor. See Warnings and Precautions (5.1) for additional guidance on the management of the risk of serious infections caused by meningococcal bacteria.**
- **Patients receiving SOLIRIS are at increased risk for invasive disease caused by *Neisseria meningitidis*, even if they develop antibodies following vaccination. Monitor patients for early signs and symptoms of serious meningococcal infections and evaluate immediately if infection is suspected.**

Because of the risk of serious meningococcal infections, SOLIRIS is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called ULTOMIRIS and SOLIRIS REMS [see Warnings and Precautions (5.2)].

CONTRAINDICATIONS

- SOLIRIS is contraindicated for initiation in patients with unresolved serious *Neisseria meningitidis* infection.

WARNINGS AND PRECAUTIONS

Serious Meningococcal Infections

SOLIRIS, a complement inhibitor, increases a patient's susceptibility to serious, life-threatening, or fatal infections caused by meningococcal bacteria (septicemia and/or meningitis) in any serogroup, including non-groupable strains. Life-threatening and fatal meningococcal infections have occurred in both vaccinated and unvaccinated patients treated with complement inhibitors.

Revaccinate patients in accordance with ACIP recommendations considering the duration of therapy with SOLIRIS. Note that ACIP recommends an administration schedule in patients receiving complement inhibitors that differs from the administration schedule in the vaccine prescribing information.

If urgent SOLIRIS therapy is indicated in a patient who is not up to date with meningococcal vaccines according to ACIP recommendations, provide the patient with antibacterial drug prophylaxis and administer meningococcal vaccines as soon as possible. Various durations and regimens of antibacterial drug prophylaxis have been considered, but the optimal durations and drug regimens for prophylaxis and their efficacy have not been studied in unvaccinated or vaccinated patients receiving complement inhibitors, including SOLIRIS. The benefits and risks of treatment with SOLIRIS, as well as those associated with antibacterial drug prophylaxis in unvaccinated or vaccinated patients, must be considered against the known risks for serious infections caused by *Neisseria meningitidis*.

Vaccination does not eliminate the risk of serious meningococcal infections, despite development of antibodies following vaccination.

Closely monitor patients for early signs and symptoms of meningococcal infection and evaluate patients immediately if infection is suspected. Inform patients of these signs and symptoms and instruct patients to seek immediate medical care if these signs and symptoms occur. Promptly treat known infections. Meningococcal infection may become rapidly life-threatening or fatal if not recognized and treated early. Consider interruption of SOLIRIS in patients who are undergoing treatment for serious meningococcal infection, depending on the risks of interrupting treatment in the disease being treated.

ULTOMIRIS and SOLIRIS REMS

Due to the risk of serious meningococcal infections, SOLIRIS is available only through a restricted program called ULTOMIRIS and SOLIRIS REMS.

Prescribers must enroll in the REMS, counsel patients about the risk of serious meningococcal infection, provide patients with REMS educational materials, assess patient vaccination status for meningococcal vaccines (against serogroups A, C, W, Y, and B) and vaccinate if needed according to current ACIP recommendations two weeks prior to the first dose of SOLIRIS. Antibacterial drug prophylaxis must be prescribed if treatment must be started urgently and the patient is not up to date with both meningococcal vaccines according to current ACIP recommendations at least two weeks prior to the first dose of SOLIRIS. Patients must receive counseling about the need to receive meningococcal vaccines and to take antibiotics as directed, the signs and symptoms of meningococcal infection, and be instructed to carry the Patient Safety Card with them at all times during and for 3 months following SOLIRIS treatment.

Further information is available at www.UltSolREMS.com or 1-888-765-4747.

Other Infections

Serious infections with *Neisseria* species (other than *Neisseria meningitidis*), including disseminated gonococcal infections, have been reported.

SOLIRIS blocks terminal complement activation; therefore, patients may have increased susceptibility to infections, especially with encapsulated bacteria, such as infections with *Neisseria meningitidis* but also *Streptococcus pneumoniae*, *Haemophilus influenzae*, and to a lesser extent, *Neisseria gonorrhoeae*. Additionally, *Aspergillus* infections have occurred in immunocompromised and neutropenic patients. Children treated with SOLIRIS may be at increased risk of developing serious infections due to *Streptococcus pneumoniae* and *Haemophilus influenzae* type b (Hib). Administer vaccinations for the prevention of *Streptococcus pneumoniae* and *Haemophilus influenzae* type b (Hib) infections according to ACIP recommendations. Patients receiving SOLIRIS are at increased risk for infections due to these organisms, even if they develop antibodies following vaccination.

Monitoring Disease Manifestations After SOLIRIS Discontinuation
Treatment Discontinuation for PNH

Monitor patients after discontinuing SOLIRIS for at least 8 weeks to detect hemolysis.

Treatment Discontinuation for aHUS

After discontinuing SOLIRIS, monitor patients with aHUS for signs and symptoms of thrombotic microangiopathy (TMA) complications for at least 12 weeks. In aHUS clinical trials, 18 patients (5 in the prospective studies) discontinued SOLIRIS treatment. TMA complications occurred following a missed dose in 5 patients, and SOLIRIS was reinitiated in 4 of these 5 patients.

Clinical signs and symptoms of TMA include changes in mental status, seizures, angina, dyspnea, or thrombosis. In addition, the following changes in laboratory parameters may identify a TMA complication: occurrence of 2,

or repeated measurement of any one of the following: a decrease in platelet count by 25% or more compared to baseline or the peak platelet count during SOLIRIS treatment; an increase in serum creatinine by 25% or more compared to baseline or nadir during SOLIRIS treatment; or, an increase in serum LDH by 25% or more over baseline or nadir during SOLIRIS treatment.

If TMA complications occur after SOLIRIS discontinuation, consider reinstatement of SOLIRIS treatment, plasma therapy [plasmapheresis, plasma exchange, or fresh frozen plasma infusion (PE/PI)], or appropriate organ-specific supportive measures.

Thrombosis Prevention and Management

The effect of withdrawal of anticoagulant therapy during SOLIRIS treatment has not been established. Therefore, treatment with SOLIRIS should not alter anticoagulant management.

Infusion-Related Reactions

Administration of SOLIRIS may result in infusion-related reactions, including anaphylaxis or other hypersensitivity reactions. In clinical trials, no patients experienced an infusion-related reaction which required discontinuation of SOLIRIS. Interrupt SOLIRIS infusion and institute appropriate supportive measures if signs of cardiovascular instability or respiratory compromise occur.

ADVERSE REACTIONS

Adverse Reactions for PNH

The most frequently reported adverse reactions in the PNH randomized trial ($\geq 10\%$ overall and greater than placebo) were: headache, nasopharyngitis, back pain, and nausea.

Adverse Reactions for aHUS

The most frequently reported adverse reactions in the aHUS single arm prospective trials ($\geq 20\%$) were: headache, diarrhea, hypertension, upper respiratory infection, abdominal pain, vomiting, nasopharyngitis, anemia, cough, peripheral edema, nausea, urinary tract infections, pyrexia.

Adverse Reactions for gMG

The most frequently reported adverse reaction in the adult gMG placebo-controlled clinical trial ($\geq 10\%$) was: musculoskeletal pain.

Adverse Reactions for NMOSD

The most frequently reported adverse reactions in the NMOSD placebo-controlled trial ($\geq 10\%$) were: upper respiratory infection, nasopharyngitis, diarrhea, back pain, dizziness, influenza, arthralgia, pharyngitis, and contusion.

DRUG INTERACTIONS

Plasmapheresis, Plasma Exchange, Fresh Frozen Plasma Infusion, or IVIg
Concomitant use of SOLIRIS with plasma exchange (PE), plasmapheresis (PP), fresh frozen plasma infusion (PE/PI), or in patients with gMG on concomitant IVIg treatment can reduce serum eculizumab concentrations and requires a supplemental dose of SOLIRIS.

Neonatal Fc Receptor Blockers

Concomitant use of SOLIRIS with neonatal Fc receptor (FcRn) blockers may lower systemic exposures and reduce effectiveness of SOLIRIS. Closely monitor for reduced effectiveness of SOLIRIS.

To report SUSPECTED ADVERSE REACTIONS contact Alexion Pharmaceuticals, Inc. at 1-844-259-6783 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

INDICATIONS

Paroxysmal Nocturnal Hemoglobinuria (PNH)

SOLIRIS is indicated for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis.

Atypical Hemolytic Uremic Syndrome (aHUS)

SOLIRIS is indicated for the treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy.

Limitation of Use

SOLIRIS is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).

Generalized Myasthenia Gravis (gMG)

SOLIRIS is indicated for the treatment of generalized myasthenia gravis (gMG) in adult and pediatric patients six years of age and older who are anti-acetylcholine receptor (AChR) antibody positive.

Neuromyelitis Optica Spectrum Disorder (NMOSD)

SOLIRIS is indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

Please see Indications & Important Safety Information on pages 5 and 6, and accompanying full [Prescribing Information](#) for SOLIRIS, including **Boxed WARNING** regarding serious and life-threatening or fatal meningococcal infections, also available on www.SOLIRIS.net.

This material is intended only for residents of the United States.

ALEXION, the Alexion logo, SOLIRIS, and ULTOMIRIS are registered trademarks of Alexion Pharmaceuticals, Inc.
© 2025, Alexion Pharmaceuticals, Inc. All rights reserved. US/ALL/1035 V4 04/2025