PRESCRIBER START FORM - NEUROLOGY

CONTACT ONESOURCE™: **PHONE:** 1.888.765.4747 8:30 AM to 8 PM ET Monday-Friday **EMAIL:** OneSource@Alexion.com **FAX:** 1.800.420.5150 **MAIL:** 100 College Street New Haven, CT 06510

ULTOMIRIS® (ravulizumab-cwvz) Injection for Intravenous Use
SOLIRIS® (eculizumab) Injection for Intravenous Use
ONESOURCE® Personalized Patient Support from Alexion

FOR PRESCRIBER

Fields in red with asterisks are required.*

STEP 1: PATIENT INFORMATION

PATIENT NAME (FIRST, LAST)*	DATE OF BIRTH (MM/DD/YYYY)*	PATIENT PHONE NUMBER*	PATIENT EMAIL

LEGAL PATIENT REPRESENTATIVE* (THIS SECTION IS REQUIRED IF PATIENT IS A MINOR)

NAME (FIRST, LAST)	PHONE NUMBER	RELATIONSHIP TO PATIENT	EMAIL

STEP 2: CLINICAL DIAGNOSIS

SOLIRIS and ULTOMIRIS are FDA approved for antibody-positive status. If a payer requires prior authorization and/or has a clinical policy, they may require proof of antibody status.

INDICATION (check one)*:

- ☐ ICD-10: G70.00 Myasthenia gravis without (acute) exacerbation
- ☐ ICD-10: G70.01 Myasthenia gravis with (acute) exacerbation
- ☐ ICD-10: G36.00 Neuromyelitis optica [Devic] (NMOSD)

ANTIBODY STATUS (check one)*:

- ☐ ANTI-AChR ANTIBODY POSITIVE (gMG)
- ☐ ANTI-AQP4 ANTIBODY POSITIVE (NMOSD)
- ☐ UNKNOWN (CONTACT ONESOURCE FOR QUESTIONS)

STEP 3: INSURANCE INFORMATION

Complete this section OR attach copies of patient's medical and pharmacy insurance card(s).*

☐ PLEASE PROVIDE SUMMARY OF BENEFIT INVESTIGATION FOR ULTOMIRIS AND SOLIRIS

☐ COPIES OF PATIENT'S INSURANCE CARD(S) ATTACHED ☐ PATIENT DOES NOT HAVE INSURANCE	PRIMARY MEDICAL INSURANCE	SECONDARY MEDICAL INSURANCE	PHARMACY COVERAGE
INSURANCE PROVIDER*			
INSURANCE PHONE #*			
CARDHOLDER NAME*			
CARDHOLDER DATE OF BIRTH*			
MEMBER ID*			
POLICY #*			
GROUP #*			
BIN #			
PCN #			

STEP 4: HEALTHCARE PRESCRIBER INFORMATION

FIRST NAME*	LAST NAME*	PROVIDER EMAIL*
ADDRESS*		PHONE NUMBER*
CITY*	STATE*	ZIP*
PRACTICE NAME	TAX ID #*	NPI #*
OFFICE CONTACT NAME	EMAIL	FAX NUMBER

STEP 5: SITE OF CARE

SELECT OPTION A OR B BELOW*:

☐ **A) PLEASE PROVIDE ASSISTANCE LOCATING AN INFUSION SITE.**

☐ **B) ASSISTANCE IS NOT NEEDED.** PATIENT WILL BE INFUSED AT: ☐ PRESCRIBER'S OFFICE ☐ INFUSION SITE (specify details below) ☐ HOME (specify specialty pharmacy below)

SITE OF CARE NAME	NPI #	TAX ID #
ADDRESS		
CITY	STATE	ZIP
OFFICE CONTACT FOR FOLLOW-UP		PHONE NUMBER

Please see Indication & Important Safety Information on page 3 and accompanying full Prescribing Information and Medication Guide for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections, also available on www.ULTOMIRIS.com.

Please see Indication & Important Safety Information on page 4 and accompanying full Prescribing Information and Medication Guide for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections, also available on www.SOLIRIS.net.

PRESCRIBER START FORM - NEUROLOGY

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ULTOMIRIS® (ravulizumab-cwvz) SOLIRIS® (eculizumab) ONESOURCE® Personalized Patient Support from Alexion

FOR PRESCRIBER

Fields in red with asterisks are required.*

PATIENT INFORMATION

PATIENT NAME (FIRST, LAST)*	DATE OF BIRTH (MM/DD/YYYY)*

STEP 6: CLINICAL INFORMATION

CHECK ALL PREVIOUS GENERALIZED MYASTHENIA GRAVIS (gMG) THERAPIES:

- ☐ AZATHIOPRINE
- ☐ MYCOPHENOLATE MOFETIL
- ☐ PYRIDOSTIGMINE
- ☐ EFGARTIGIMOD
- ☐ PLASMAPHERESIS
- ☐ RITUXIMAB
- ☐ IVIg
- ☐ PREDNISONE
- ☐ OTHER

MGFA CLASSIFICATION: _____

CURRENT MG-ADL SCORE: _____

CHECK ALL PREVIOUS NEUROMYELITIS OPTICA SPECTRUM DISORDER (NMOSD) THERAPIES:

- ☐ AZATHIOPRINE
- ☐ METHOTREXATE
- ☐ RITUXIMAB
- ☐ OTHER
- ☐ CYCLOPHOSPHAMIDE
- ☐ MITOXANTRONE
- ☐ SATRALIZUMAB
- ☐ INEBILIZUMAB
- ☐ MYCOPHENOLATE MOFETIL
- ☐ STEROID

NUMBER OF RELAPSES IN LAST 12 MONTHS: _____ 24 MONTHS: _____

EDSS SCORE: _____

Abbreviations: AChR, acetylcholine receptor; EDSS, Expanded Disability Status Scale; IVIg, intravenous immunoglobulin; MG-ADL, Myasthenia Gravis Activities of Daily Living; MGFA, Myasthenia Gravis Foundation of America.

STEP 7: PRESCRIPTION

▶ **YOU MAY USE THIS SECTION TO PROVIDE A PRESCRIPTION FOR ULTOMIRIS OR SOLIRIS, OR YOU MAY PROVIDE A SEPARATE PRESCRIPTION.**

☐ Rx **ULTOMIRIS** 100 mg/mL HCPCS CODE: J1303 PER UNIT

PATIENT WEIGHT: _____

LOADING DOSE:

SIG: INFUSE INTRAVENOUSLY _____ mg ON DAY 0. COVERS THE PATIENT FOR THE FIRST 2 WEEKS.

☐ OTHER: _____

QTY OF 300 mg/3 mL

VIALS: _____ REFILLS: 0

MAINTENANCE DOSE:

SIG: INFUSE INTRAVENOUSLY _____ mg EVERY 8 WEEKS. START 2 WEEKS AFTER COMPLETION OF LOADING DOSE.

☐ OTHER: _____

QTY OF 300 mg/3 mL

VIALS: _____ REFILLS: _____

QTY OF 1100 mg/11 mL

VIALS: _____ REFILLS: _____

☐ Rx **SOLIRIS** 2 mg/mL HCPCS CODE: J1299 PER UNIT

For pediatric patients, you must provide a separate prescription

LOADING DOSE:

SIG: INFUSE INTRAVENOUSLY _____ mg WEEKLY FOR THE FIRST 4 WEEKS, FOLLOWED BY _____ mg FOR THE 5TH WEEK.

☐ OTHER: _____

QTY OF 300 mg/30 mL

VIALS: _____ REFILLS: 0

MAINTENANCE DOSE:

SIG: INFUSE INTRAVENOUSLY _____ mg EVERY 2 WEEKS. START 2 WEEKS AFTER THE 5TH WEEK'S DOSE IS COMPLETE.

☐ OTHER: _____

QTY OF 300 mg/30 mL

VIALS: _____ REFILLS: _____

STEP 8: PATIENT VACCINATION HISTORY

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

AFTER YOU COMPLETE THIS FORM:

Provide vaccination history to confirm that the patient has received the appropriate vaccinations or antibacterial drug prophylaxis prior to starting therapy

- ✓ Enter vaccination information directly in the REMS portal at www.NeuroUltSolREMS.com

OR

- ✓ Send VAR (Vaccination Administration Record) via FAX to 1-866-750-0481 or EMAIL to UltSol@AlexionREMS.com

YOU MAY SKIP THIS STEP IF YOU HAVE ALREADY PROVIDED THIS INFORMATION

☐ My patient needs **VACCINATION SUPPORT** from OneSource

STEP 9: PRESCRIBER CERTIFICATION

By signing below, I attest that: (i) I am prescribing the above mentioned product for an on-label diagnosis for the patient identified above based on my clinical judgment that it is medically necessary for the diagnosis identified on this form and I will be supervising the patient's treatment; (ii) I am an authorized prescriber under applicable law and I have verified and complied with all applicable prescription requirements; (iii) I am authorizing Alexion to forward the patient's prescription to a pharmacy by any means permitted under applicable law; (iv) The patient and/or their legal representative is aware of, has consented to, and has authorized my disclosure of their information to OneSource for the scope of the program, including but not limited to benefit investigation and access support. OneSource will contact the patient for completing the enrollment in the program. (v) I am under no obligation to prescribe any Alexion products and I have not received, nor will I receive, any benefit from Alexion for prescribing any products; and (vi) the information provided on this form is complete, current, and accurate to the best of my knowledge. I also acknowledge that Alexion will use and share the personal data collected about me (as the prescriber) in accordance with the Privacy Notice on the Alexion website at https://Alexion.com/Legal#privacy.

SIGN ONE*

PRESCRIBER'S SIGNATURE (NO STAMPS) - **DISPENSE AS WRITTEN** DATE (MM/DD/YYYY)

PRESCRIBER'S SIGNATURE (NO STAMPS) - **MAY SUBSTITUTE** * DATE (MM/DD/YYYY)

*Only applicable for substitution with other Alexion products as available.

Please verify your local prescribing requirements (eg, New York prescribers must provide a separate prescription).

Please see Indication & Important Safety Information on page 3 and accompanying full Prescribing Information and Medication Guide for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections, also available on www.ULTOMIRIS.com.

Please see Indication & Important Safety Information on page 4 and accompanying full Prescribing Information and Medication Guide for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections, also available on www.SOLIRIS.net.

INDICATIONS & IMPORTANT SAFETY INFORMATION FOR ULTOMIRIS

INDICATIONS

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

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*. Patients receiving ULTOMIRIS are at increased risk for infections due to these organisms, even if they develop antibodies following vaccination.

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 gMG

Most common adverse reactions in adult patients with gMG (incidence ≥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 ≥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 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.

Please see accompanying full Prescribing Information for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

INDICATIONS & IMPORTANT SAFETY INFORMATION FOR SOLIRIS® (eculizumab)

INDICATIONS

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.

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.

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 gMG

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

Adverse Reactions for NMOSD

The most frequently reported adverse reactions in the NMOSD placebo-controlled trial (≥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.

Please see accompanying full Prescribing Information for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

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

ALEXION® AstraZeneca Rare Disease