Limitation of Use

Soliris is a complement inhibitor indicated for:

- The treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis (1.1).
- The treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy (1.2).

Soliris is contraindicated in:

- Patients with unresolved serious Neisseria meningitidis infection (4).
- Patients who are not currently vaccinated against Neisseria meningitidis, unless the risks of delaying Soliris treatment outweigh the risks of developing a meningococcal infection (5.1).

Soliris is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS). Under the Soliris REMS, prescribers must enroll in the program (5.2).

INDICATIONS AND USAGE

Soliris is a complement inhibitor indicated for:

- Atypical Hemolytic Uremic Syndrome (aHUS) to inhibit complement-mediated nephropathy (1).

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

DOSAGE AND ADMINISTRATION

• Only administer as an intravenous infusion.

PfN Dosage Regimen: (2.1)

Only administer as an intravenous infusion.

aHUS Dosage Regimen: (2.2)

300 mg single-dose vials each containing 30 mL of 10 mg/mL sterile, preservative-free solution (3).

CONTRAINDICATIONS

Soliris is contraindicated in:

- Patients with unresolved serious Neisseria meningitidis infection (4).
- Patients who are not currently vaccinated against Neisseria meningitidis, unless the risks of delaying Soliris treatment outweigh the risks of developing a meningococcal infection (5.1).

WARNINGS AND PRECAUTIONS

- Discontinue Soliris in patients who are being treated for serious meningococcal infections.
- Use caution when administering Soliris to patients with any other systemic infection (5.2).

ADVERSE REACTIONS

The most frequently reported adverse reactions in the PNH randomized trial (≥10% overall and greater than placebo) are: headache, nasopharyngitis, back pain, and nausea (6.1).

The most frequently reported adverse reactions in aHUS single arm prospective trials (≥20%) are: headache, diarrhea, hypertension, upper respiratory infection, abdominal pain, vomiting, nasopharyngitis, anemia, cough, peripheral edema, nausea, urinary tract infections, pyelitis (6.1).

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.

Full prescribing information: CONTENTS*

INDICATIONS AND USAGE

1.1 Paroxysmal Nocturnal Hemoglobinuria (PNH)
1.2 Atypical Hemolytic Uremic Syndrome (aHUS)

DOSAGE AND ADMINISTRATION

2.1 Recommended Dosage Regimen - PNH
2.2 Recommended Dosage Regimen - aHUS
2.3 Preparation and Administration
2.4 Administration

DOSAGE FORMS AND STRENGTHS

PNH Dosage Regimen: (2.1)

aHUS Dosage Regimen: (2.2)

OVERDOSAGE

PATIENT COUNSELING INFORMATION

HOW SUPPLIED/STORAGE AND HANDLING

CLINICAL PHARMACOLOGY

NONCLINICAL TOXICOLOGY

CLINICAL STUDIES

PfN

aHUS

HUMAN PHARMACOLOGY

Human Pharmacology

Human experience with Soliris is limited to PNH and aHUS. The information available from treatment of patients with PNH or aHUS is primarily from clinical trials, and real-world experiences of patients treated with Soliris have been obtained through post-approval surveillance. There are no adequate and well-controlled studies in pregnancy in humans or animal studies demonstrating safe and effective use of Soliris in pregnancy.

Because animal reproduction studies are not always predictive of human response, Soliris should be given to a pregnant woman only if clearly needed. See 17 Patient Counseling Information and Medication Guide.

In a pharmacokinetic study, the mean total plasma exposure (AUC) of eculizumab and its metabolites was increased by 24% in healthy volunteers with hepatic impairment (Child-Pugh A) compared to healthy volunteers with normal hepatic function. No dose adjustment is required in hepatic impairment. See 12.3 Pharmacokinetics in full prescribing information for additional guidance on the management of the risk of meningococcal infection.

In a pharmacokinetic study, the mean total plasma exposure (AUC) of eculizumab was increased by 119% in healthy volunteers with renal impairment (creatinine clearance ≤60 mL/min) compared to healthy volunteers with normal renal function. See 12.3 Pharmacokinetics in full prescribing information for additional guidance on the management of the risk of meningococcal infection.

Due to the potential for hemolysis in patients with aHUS, hematology laboratory evaluations are recommended for the first 6 months of therapy. See 6.3 Postmarketing Experience in full prescribing information for additional guidance on the management of the risk of meningococcal infection.

Due to the potential for hemolysis in patients with aHUS, hematology laboratory evaluations are recommended for the first 6 months of therapy.
Supplemental dosing of Soliris is required in the setting of concomitant support with PE/PI (plasmapheresis or plasma exchange; or fresh frozen plasma infusion) (Table 2).

<table>
<thead>
<tr>
<th>Table 2: Supplemental dose of Soliris after PE/PI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of Intervention</td>
</tr>
<tr>
<td>----------------------</td>
</tr>
<tr>
<td>Phospholipid or plasma exchange</td>
</tr>
<tr>
<td>Fresh frozen plasma infusion</td>
</tr>
</tbody>
</table>

2.3 Preparation and Administration

Dilute Soliris to a final concentration of 5 mg/mL by adding the appropriate amount (equal volume of diluent to drug volume) of 0.9% Sodium Chloride Injection, USP; 0.45% Sodium Chloride Injection, USP; 5% Dextrose in Water Injection, USP; or Ringer's Injection, USP to the infusion bag. The final admixed Soliris 5 mg/mL infusion volume is 60 mL for 300 mg doses, 120 mL for 600 mg doses, 180 mL for 900 mg doses or 240 mL for 1200 mg doses (Table 3).

Table 3: Preparation and Reconstitution of Soliris

<table>
<thead>
<tr>
<th>Soliris Dose</th>
<th>Diluent Volume</th>
<th>Final Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>300 mg</td>
<td>30 mL</td>
<td>60 mL</td>
</tr>
<tr>
<td>600 mg</td>
<td>60 mL</td>
<td>120 mL</td>
</tr>
<tr>
<td>900 mg</td>
<td>90 mL</td>
<td>180 mL</td>
</tr>
<tr>
<td>1200 mg</td>
<td>120 mL</td>
<td>240 mL</td>
</tr>
</tbody>
</table>

Gently invert the infusion bag containing the diluted Soliris solution to ensure thorough mixing of the product and diluent. Discard any unused portion left in a vial, as the product contains no preservatives.

Prior to administration, the admixture should be allowed to adjust to room temperature (18–25°C, 64–77°F). The admixture must not be heated in a microwave or with any heat source other than ambient air. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

2.4 Administration

Do Not Administer As An Intravenous Push or Bolus Injection

Administer the Soliris admixture by intravenous infusion over 35 minutes in adults and 1 to 4 hours in pediatric patients via gravity feed, a syringe-type pump, or an infusion pump. Admixed solutions of Soliris are stable for 24 hours at 2–8°C (36–46°F) and at room temperature. If an adverse reaction occurs during the administration of Soliris, the infusion may be slowed or stopped at the discretion of the physician. If the infusion is slowed, the total infusion time should not exceed two hours in adults. Monitor the patient for at least one hour following completion of the infusion for signs or symptoms of an infusion reaction.

3 DOSAGE FORMS AND STRENGTHS

Soliris is supplied as 300 mg single-dose vials each containing 30 mL of 10 mg/mL sterile, preservative-free ezuclizumab solution.

4 CONTRAINdications

Soliris is contraindicated in:

- Patients with unresolved serious Neisseria meningitidis infection
- Patients who are not currently vaccinated against Neisseria meningitidis, unless the risks of delaying Soliris treatment outweigh the risks of developing a meningococcal infection [see Warnings and Precautions (5.1)].

5 WARNINGS AND PRECAUTIONs

5.1 Serious Meningococcal Infections

Life-threatening and fatal meningococcal infections have occurred in patients treated with Soliris. The use of Soliris increases a patient’s susceptibility to serious meningococcal infections (septicaemia and/or meningitis). Vaccinate for meningococcal disease according to the most current Advisory Committee on Immunization Practices (ACIP) recommendations for patients with complement deficiencies. Revaccinate patients in accordance with ACIP recommendations, considering the duration of Soliris therapy.

Immunize patients without a history of meningococcal vaccination at least 2 weeks prior to receiving the first dose of Soliris. If urgent Soliris therapy is indicated in an unvaccinated patient, administer meningococcal vaccine(s) as soon as possible.

In prospective clinical studies, 75/100 patients with aHUS who were treated with Soliris less than 2 weeks after meningococcal vaccination and 64 of these 75 patients received antibiotics for prophylaxis of meningococcal infection until at least 2 weeks after meningococcal vaccination. The benefits and risks of antibiotic prophylaxis for prevention of meningococcal infections in patients receiving Soliris have not been established. Vaccination reduces, but does not eliminate, the risk of meningococcal infections. In clinical studies, 2 out of 196 PNH patients developed serious meningococcal infections while receiving treatment with Soliris; both had been vaccinated [see Adverse Reactions (6.1)]. In clinical studies among non-PNH patients, meningococcal meningitis occurred in one unvaccinated patient. In clinical studies among patients without PNH, meningococcal meningitis occurred in one previously vaccinated patient enrolled in the retrospective aHUS study during the post-dose follow-up period [see Warnings and Precautions (5.1)].

PNH

The data described below reflect exposure to Soliris in 196 adult patients with PNH, age 18–85, of whom 55% were female. All had signs or symptoms of intravascular hemolysis. Soliris was studied in a placebo-controlled clinical study (n=43) in patients with PNH, aHUS, and 92 adult patients treated with Soliris in the open-label extension study of a 422-patient randomized clinical study involving 415 patients with aHUS. Among 193 patients with PNH treated with Soliris in the single arm clinical study or the follow-up study, the adverse reactions were similar to those reported in the placebo-controlled clinical study. Serious adverse reactions occurred among 16% of the patients in these studies. The most common serious adverse reactions were: viral infection (2%), headache (2%), anemia (2%), and pyrexia (2%).

5.2 Soliris REMS

Because of the risk of meningococcal infections, Soliris is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS). Under the Soliris REMS, prescribers must enroll in the program. Prescribers must counsel patients about the risk of meningococcal infection, provide the patients with the REMS educational materials, and ensure patients are vaccinated with a meningococcal vaccine.

Enrollment in the Soliris REMS program and additional information are available by telephone: 1-888-SOLIRIS (1-888-765-4747) or at solirisrems.com.

5.3 Other Infections

Soliris blocks terminal complement activation; therefore patients may have increased susceptibility to infections, especially with encapsulated bacteria. 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 influenza type b (Hib). Administer vaccinations for the prevention of Streptococcus pneumoniae and Haemophilus influenza type b (Hib) infections according to ACIP guidelines. Use caution when administering Soliris to patients with any systemic infection [see Warnings and Precautions (5.1)].

5.4 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 4 patients, and Soliris was reinitiated in 5 of these 4 patients. Clinical signs and symptoms of TMA include changes in mental status, seizures, anuria, dyspnea, or thrombosis. In addition, the following changes in laboratory parameters may indicate a TMA complication: occurrence of five, or repeated measurement of any one of the following: a decrease in platelet count by 25% or more compared to baseline or 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 reinstitution of Soliris treatment, plasma therapy [plasmapheresis, plasma exchange, or fresh frozen plasma infusion (PF-E/P)], or appropriate organ-specific supportive measures.

5.5 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.

6 ADVERSE REACTIONS

The following serious adverse reactions are discussed in greater detail in other sections of the labeling:

- Serious Meningococcal Infections [see Warnings and Precautions (5.1)]
- Other Infections [see Warnings and Precautions (5.3)]
- Monitoring Disease Manifestations After Soliris Discontinuation [see Warnings and Precautions (5.4)]
- Thrombosis Prevention and Management [see Warnings and Precautions (5.5)]
- Infusion Reactions [see Warnings and Precautions (5.6)]

6.1 Clinical Trial Experience

Because clinical trials were conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in clinical trials of another drug and may not reflect the rates observed in practice.

Meningococcal infections are the most important adverse reactions experienced by patients receiving Soliris. In PNH clinical studies, two patients experienced meningococcal sepsis. Both patients had previously received a meningococcal vaccine in a clinical study among patients without PNH, meningococcal meningitis occurred in one unvaccinated patient. Meningococcal sepsis occurred in one previously vaccinated patient enrolled in the retrospective aHUS study during the post-dose follow-up period [see Warnings and Precautions (5.1)].

PNH

The data described below reflect exposure to Soliris in 196 adult patients with PNH, age 18–85, of whom 55% were female. All had signs or symptoms of intravascular hemolysis. Soliris was studied in a placebo-controlled clinical study (n=43) in patients with PNH, aHUS, and 92 adult patients treated with Soliris in the open-label extension study of a 422-patient randomized clinical study involving 415 patients with aHUS. Among 193 patients with PNH treated with Soliris in the single arm clinical study or the follow-up study, the adverse reactions were similar to those reported in the placebo-controlled clinical study. Serious adverse reactions occurred among 4 (2%) patients receiving Soliris and 9 (21%) patients receiving placebo. The serious reactions included infections and progression of PNH. No deaths occurred in the study and no patients receiving Soliris experienced a thrombotic event; one thrombotic event occurred in a patient receiving placebo.

Among 193 patients with PNH treated with Soliris in the single arm clinical study or the follow-up study, the adverse reactions were similar to those reported in the placebo-controlled clinical study. Serious adverse reactions occurred among 16% of the patients in these studies. The most common serious adverse reactions were: viral infection (2%), headache (2%), anemia (2%), and pyrexia (2%).

aHUS

The safety of Soliris therapy in patients with aHUS was evaluated in four prospective, single-arm studies, three in adult and adolescent patients (aHUS Studies 1, 2, and 4), one in pediatric and adolescent patients (aHUS Study 5) and one retrospective study (aHUS Study 3).
The data described below were derived from 78 adult and adolescent patients with aHUS enrolled in aHUS Study 1, aHUS Study 2, and aHUS Study 4. All patients received the recommended dosage of Soliris. Median exposure was 67 weeks (range: 2-145 weeks). Table 5 summarizes all adverse events reported in at least 10% of patients in aHUS Studies 1, 2, and 4 combined.

Table 5: Per Patient Incidence of Adverse Events in 10% or More Adult and Adolescent Patients Enrolled in aHUS Study 1, aHUS Study 2 and aHUS Study 4 Separately and in Total

<table>
<thead>
<tr>
<th>MedDRA vera. 15.1</th>
<th>Number (%) of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Vascular Disorders</strong></td>
<td></td>
</tr>
<tr>
<td>Hypertension*</td>
<td>10 (69) 9 (45) 7 (17) 26 (33)</td>
</tr>
<tr>
<td>Hypotension</td>
<td>2 (12) 4 (20) 7 (17) 13 (17)</td>
</tr>
<tr>
<td><strong>Infections and Infestations</strong></td>
<td></td>
</tr>
<tr>
<td>Bronchitis</td>
<td>3 (18) 2 (10) 4 (10) 9 (12)</td>
</tr>
<tr>
<td>Nasopharyngitis</td>
<td>3 (18) 11 (55) 7 (17) 21 (27)</td>
</tr>
<tr>
<td>Gastroenteritis</td>
<td>3 (18) 4 (20) 2 (5) 9 (12)</td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>5 (29) 6 (40) 2 (5) 9 (12)</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>5 (35) 3 (15) 8 (20) 17 (22)</td>
</tr>
<tr>
<td><strong>Gastrointestinal Disorders</strong></td>
<td></td>
</tr>
<tr>
<td>Diarrhea</td>
<td>8 (47) 6 (40) 12 (32) 29 (37)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>8 (47) 9 (45) 6 (15) 23 (30)</td>
</tr>
<tr>
<td><strong>Respiratory, Thoracic and Mediastinal Disorders</strong></td>
<td></td>
</tr>
<tr>
<td>Asthma</td>
<td>4 (24) 3 (15) 5 (12) 12 (15)</td>
</tr>
<tr>
<td><strong>Musculo-skeletal and Connective Tissue Disorders</strong></td>
<td></td>
</tr>
<tr>
<td>Muscle spasms</td>
<td>2 (11) 2 (10) 7 (17) 10 (13)</td>
</tr>
<tr>
<td><strong>Skin and Subcutaneous Tissue Disorders</strong></td>
<td></td>
</tr>
<tr>
<td>Rash</td>
<td>4 (22) 2 (10) 7 (17) 10 (13)</td>
</tr>
<tr>
<td><strong>Nervous System Disorders</strong></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td>3 (17) 5 (30) 5 (12) 8 (13)</td>
</tr>
<tr>
<td><strong>Infections and Infestations</strong></td>
<td></td>
</tr>
<tr>
<td>Bronchitis</td>
<td>3 (18) 2 (10) 4 (10) 9 (12)</td>
</tr>
<tr>
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<td>3 (18) 11 (55) 7 (17) 21 (27)</td>
</tr>
<tr>
<td>Gastroenteritis</td>
<td>3 (18) 4 (20) 2 (5) 9 (12)</td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>5 (29) 6 (40) 2 (5) 9 (12)</td>
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<tr>
<td><strong>Gastrointestinal Disorders</strong></td>
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</tr>
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<td>8 (47) 6 (40) 12 (32) 29 (37)</td>
</tr>
<tr>
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<td>8 (47) 9 (45) 6 (15) 23 (30)</td>
</tr>
<tr>
<td><strong>Respiratory, Thoracic and Mediastinal Disorders</strong></td>
<td></td>
</tr>
<tr>
<td>Asthma</td>
<td>4 (24) 3 (15) 5 (12) 12 (15)</td>
</tr>
<tr>
<td><strong>Musculo-skeletal and Connective Tissue Disorders</strong></td>
<td></td>
</tr>
<tr>
<td>Muscle spasms</td>
<td>2 (11) 2 (10) 7 (17) 10 (13)</td>
</tr>
<tr>
<td><strong>Nervous System Disorders</strong></td>
<td></td>
</tr>
</tbody>
</table>

In aHUS Study 5, 59% (13/22) of patients experienced a serious adverse event (SAE). The most commonly reported SAEs were hypertension (9%), vocal gastroenteritis (9%), pyrexia (9%), and upper respiratory infection (9%). One patient discontinued Soliris due to an adverse event (severe agitation).

Analysis of retrospectively collected adverse event data from pediatric and adult patients enrolled in aHUS Study 3 (N=30) revealed a safety profile that was similar to that which was observed in the two prospective studies. aHUS Study 3 included 19 pediatric patients less than 16 years of age. Overall, the safety of Soliris in pediatric patients with aHUS enrolled in Study 3 appeared similar to that observed in adult patients. The most common (>15%) adverse events occurring in pediatric patients are presented in Table 7.

Table 7: Adverse Reactions Occurring in at Least 15% of Patients Less than 18 Years of Age Enrolled in aHUS Study 3

<table>
<thead>
<tr>
<th>MedDRA vera. 11.0</th>
<th>Number (%) of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cardiac Disorders</strong></td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>4 (22) 2 (10) 7 (17) 10 (13)</td>
</tr>
<tr>
<td><strong>Respiratory, Thoracic and Mediastinal Disorders</strong></td>
<td></td>
</tr>
<tr>
<td>Asthma</td>
<td>4 (22) 2 (10) 7 (17) 10 (13)</td>
</tr>
<tr>
<td><strong>Musculo-skeletal and Connective Tissue Disorders</strong></td>
<td></td>
</tr>
<tr>
<td>Muscle spasms</td>
<td>2 (11) 2 (10) 7 (17) 10 (13)</td>
</tr>
<tr>
<td><strong>Nervous System Disorders</strong></td>
<td></td>
</tr>
</tbody>
</table>

6.2 Immunogenicity

As with all proteins, there is a potential for immunogenicity with eculizumab. The immunogenicity of Soliris has been evaluated using two different immunoassays for the detection of anti-eculizumab antibodies: a direct enzyme-linked immunoblot assay (ELISA) using the Fab fragment of eculizumab as target was used for the PNH indication; and an electro-chemiluminescence (ECL) bridging assay using the eculizumab whole molecule as target was used for the aHUS indication, as well as for additional patients with PNH. In the PNH population, antibodies to Soliris were detected in 3/196 (2%) patients with PNH treated with Soliris using the ELISA assay and in 5/161 (3%) patients treated with Soliris using the ECL assay. In patients with aHUS treated with Soliris, antibodies to Soliris were detected in 3/100 (3%) using the ECL assay. An ECL based neutralizing HAMA assay with a low sensitivity of 0.2 mcg/ml was performed to detect neutralizing antibodies for the 3 patients with aHUS and also for the 5 patients with PNH with positive samples using the ECL assay. 2/161 patients in the PNH group (1.2%) and 1/100 patients in the aHUS group (1%) had low positive values for neutralizing antibodies. No apparent correlation of antibody development to clinical response was observed in either indication. The immunogenicity data reflect the percentage of patients whose test results were considered positive for antibodies to Soliris in an ELISA-based assay and/or an ECL-based assay and are highly dependent on the sensitivity and specificity of the assay used. Additionally, the observed incidence of antibody positivity in the assay may be influenced by several factors including sample handling, timing of sample collection, concomitant medications and underlying disease. For these reasons, comparison of the incidence of antibodies to Soliris with the incidence of antibodies to other products may be misleading.

6.3 Postmarketing Experience

The following adverse reactions have been identified during post-approval use of Soliris. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to Soliris exposure. Cases of serious or fatal meningococcal infections have been reported.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C

Risk Summary

There are no adequate and well-controlled studies of Soliris in pregnant women. Soliris, a recombinant IgG molecule (humanized anti-C5 antibody), is expected to cross the placenta. Animal studies using a mouse analogue of the Soliris molecule (murine anti-C5 antibody) showed increased rates of developmental abnormalities and an increased rate of dead and moribund offspring at doses 2-8 times the human dose. Soliris should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Animal Data

Animal reproduction studies were conducted in mice using doses of a murine anti-C5 antibody that approximated 2-4 times (low dose) and 4-8 times (high dose) the recommended human Soliris dose, based on a body weight comparison. When animal exposure to the antibody occurred in the time period from before mating until early organogenesis, the potential benefit justifies the potential risk to the fetus.

8.3 Nursing Mothers

It is not known whether Soliris is excreted into human milk. IgG is excreted in human milk, so it is expected that Soliris will be present in human milk. However, published data suggest that antibodies in human milk do not enter...
the neonatal and infant circulation in substantial amounts. Caution should be exercised when Soliris is administered to a patient
life. To achieve a designation of hemoglobin stabilization, a patient had to maintain a hemoglobin concentration above
the hemoglobin-set point and avoid any RBC transfusion for the entire 26 week period. Hemolysis was monitored mainly
by the measurement of serum LDH levels, and the proportion of PNH RBCs was monitored by flow cytometry. Patients receiving
anticoagulants and systemic corticosteroids at baseline continued these interventions. Major baseline characteristics were balanced (see Table 8).

<table>
<thead>
<tr>
<th>Table 8: PNH Study 1 Patient Baseline Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parameter</td>
</tr>
<tr>
<td>Mean age (SD)</td>
</tr>
<tr>
<td>Gender - female (%)</td>
</tr>
<tr>
<td>History of aplastic anemia or myelodysplastic syndrome (%)</td>
</tr>
<tr>
<td>Patients with history of thrombosis (events)</td>
</tr>
<tr>
<td>Concomitant anticoagulants (%)</td>
</tr>
<tr>
<td>Concomitant steroids/immunosuppressant treatments (%)</td>
</tr>
<tr>
<td>Packed RBC units transfused per patient in previous 12 months (median (Q1,Q3))</td>
</tr>
<tr>
<td>Mean-High level (g/dL) at arbopt (SD)</td>
</tr>
<tr>
<td>Pre-treatment Hb levels (median)</td>
</tr>
<tr>
<td>Free hemoglobin at baseline (median, mg/dL)</td>
</tr>
</tbody>
</table>

Patients treated with Soliris had significantly reduced (p < 0.001) hemolysis resulting in improvements as indicated by increased hemoglobin stabilization and reduced need for RBC transfusions compared to placebo treated patients (see Table 9). These effects were seen among patients within each of the three pre-study RBC transfusion strata (4 - 14 units; 15 - 25 units; > 25 units). After 5 weeks of Soliris treatment, patients reported less fatigue and improved health-related quality of life. Because of the study sample size and duration, the effects of Soliris on TMA events could not be determined.

<table>
<thead>
<tr>
<th>Table 9: PNH Study 1 Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
</tr>
<tr>
<td>Percentage of patients with stabilized hemoglobin levels</td>
</tr>
<tr>
<td>Packed RBC units transfused per patient (median)</td>
</tr>
<tr>
<td>LDH levels at end of study (median, U/L)</td>
</tr>
<tr>
<td>Free hemoglobin at end of study (median, mg/dL)</td>
</tr>
</tbody>
</table>

Study 2 and Extension Study: PNH patients with at least one transfusion in the prior 24 months and at least 30,000 platelets/microliter received Soliris over a 52-week period. Concomitant medications included anti-thrombotic agents in 63% of the patients and systemic corticosteroids in 75% of the patients. Overall, 96 of the 97 enrolled patients completed the study; one patient died following a thrombotic event. A reduction in intravascular hemolysis as measured by serum LDH levels was sustained during the treatment period and resulted in a reduced need for RBC transfusion and less fatigue. 187 Soliris-treated PNH patients were enrolled in a long-term extension study. All patients sustained a reduction in intravascular hemolysis over a total study exposure of 256 weeks, including the 52-week extension. There were fewer thrombotic events with Soliris treatment compared to during the same period of time prior to treatment. However, the majority of patients received concomitant anticoagulants; the effects of anticoagulant withdrawal during Soliris therapy was not studied (see Warnings and Precautions (5.4)).

14.2 Atypical Hemolytic Uremic Syndrome (aHUS)

Five single-arm studies (four prospective [aHUS Studies 1, 2, 4, and 5] and one retrospective [aHUS Study 3]) evaluated the safety and efficacy of Soliris for the treatment of aHUS. Patients with aHUS received meningococcal vaccination prior to receipt of Soliris or received prophylactic treatment with antibiotics within 2 weeks after vaccination. In all studies, the dose of Soliris in adults and adolescent patients was 800 mg every 7 ± 2 days for 4 weeks, followed by 1200 mg 7 ± 2 days later, then 1200 mg every 4 ± 2 days thereafter. The dosage regimen for pediatric patients weighing less than 40 kg enrolled in aHUS Study 3 and Study 5 was based on body weight (see Dosage and Administration (2.2)). Eculizumab was well tolerated based on thrombotic microangiopathy (TMA) endpoints.

Endpoints related to TMA included the following:
- Platelet count change from baseline
- Hematologic normalization (maintenance of normal platelet counts and LDH levels for at least four weeks)
- Complete TMA response (hematologic normalization plus at least a 25% reduction in serum creatinine for a minimum of four months)
- TMA-event free status absence for at least 12 weeks of a decrease in platelet count of >5% from baseline, plasma exchange or plasma infusions, and new dialysis requirements
- Daily TMA intervention rate defined as the number of plasma exchange or plasma infusions and the number of new dialyses required per patient per day

aHUS Resistant to PE/Pi (aHUS Study 1)

aHUS Study 1 enrolled patients who displayed signs of thrombotic microangiopathy (TMA) despite receiving at least four PE/Pi treatments the week prior to screening. One patient had no PE/Pi the week prior to screening because of PE/Pi intolerance. In order to qualify for enrollment, patients were required to have a platelet count > 150 x 10^9/L (min, max) < 1 (<1, 4) evidence of hemolysis such as an elevation in serum LDH, and serum creatinine above the upper limits of normal, without the need for chronic dialysis. The median patient age was 26 (range: 17 to 68) years. Enrolled patients in aHUS Study 1 were required to have ADAMTS13 activity level above 5%; observed range of values in the trial were 70%-121%. Seventy-six percent of patients had an identified complement regulatory factor mutation or auto-antibody. Study 1 summarizes the key baseline clinical and disease-related characteristics of patients enrolled in aHUS Study 1.

<table>
<thead>
<tr>
<th>Table 10: Baseline Characteristics of Patients Enrolled in aHUS Study 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parameter</td>
</tr>
<tr>
<td>N = 17</td>
</tr>
<tr>
<td>Time from aHUS diagnosis until screening in months, median (min, max)</td>
</tr>
<tr>
<td>Time from current clinical TMA manifestation until screening in months, median (min, max)</td>
</tr>
<tr>
<td>Baseline platelet count (x 10^9/L), median (range)</td>
</tr>
<tr>
<td>Baseline LDH (U/L), median (range)</td>
</tr>
</tbody>
</table>

Patients in aHUS Study 1 received Soliris for a minimum of 26 weeks. In aHUS Study 1, the median duration of Soliris therapy was approximately 100 weeks (range: 2 weeks to 145 weeks). Renal function, as measured by eGFR, was improved and maintained during Soliris therapy. The mean eGFR (SD) increased from 23 ± 15 mL/min/1.73m² at baseline to 56 ± 40 mL/min/1.73m² by 26 weeks; this effect was maintained through 52 weeks. The median patient age at baseline was 30 ± 30 mL/min/1.73m². Four of the five patients who required dialysis at baseline were able to discontinue dialysis.
Reduction in terminal complement activity and an increase in platelet count relative to baseline were observed after commencement of Soliris. Soliris reduced signs of complement-mediated TMA activity, as shown by an increase in mean platelet counts from baseline to 26 weeks. In aHUS Study 1, mean platelet count (± SD) increased from 109 ± 32 x10^9/L at baseline to 169 ± 72 x10^9/L by one week; this effect was maintained through 26 weeks (210 ± 68 x10^9/L) and 2 years (200 ± 51 x10^9/L). When treatment was continued for more than 26 weeks, two additional patients achieved Hematologic Normalization as well as Complete TMA response. Hematologic Normalization and Complete TMA response were maintained by all responders. In aHUS Study 1, responses to Soliris were similar in patients with and without identified mutations in genes encoding complement regulatory factor proteins. Table 11 summarizes the efficacy results for aHUS Study 1.

Table 11: Efficacy Results for aHUS Study 1

<table>
<thead>
<tr>
<th>Efficacy Parameter</th>
<th>aHUS Study 1 at 26 wks</th>
<th>aHUS Study 1 at 2 yrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete TMA response, n (%)</td>
<td>N = 17</td>
<td>N = 17</td>
</tr>
<tr>
<td>eGFR improvement &gt;15 mL/min/1.73 m^2, n (%)</td>
<td>11 (63)</td>
<td>13 (77)</td>
</tr>
<tr>
<td>Median duration of complete TMA response, weeks (range)</td>
<td>38 (25, 56)</td>
<td>99 (25, 139)</td>
</tr>
<tr>
<td>Hematologic normalization, n (%)</td>
<td>13 (76)</td>
<td>15 (88)</td>
</tr>
<tr>
<td>Median duration of hematologic normalization, weeks (range)</td>
<td>37 (25, 62)</td>
<td>99 (25, 145)</td>
</tr>
<tr>
<td>Daily TMA intervention rate, median (range)</td>
<td>0.82 (0.0, 1.52)</td>
<td>0.82 (0.0, 1.52)</td>
</tr>
<tr>
<td>On eculizumab treatment</td>
<td>0.0 (0, 0.31)</td>
<td>0.0 (0, 0.36)</td>
</tr>
</tbody>
</table>

1 At data cut-off (September 8, 2010).
2 At data cut-off (April 20, 2012).

Patients in aHUS Study 2 received Soliris for 26 weeks. In aHUS Study 2, the median duration of Soliris therapy was approximately 114 weeks (range: 26 to 129 weeks).

Reduction in terminal complement activity and an increase in platelet count relative to baseline were observed after commencement of Soliris. Soliris reduced signs of complement-mediated TMA activity, as shown by an increase in mean platelet counts from baseline to 26 weeks. In aHUS Study 2, mean platelet count (± SD) increased from 171 ± 83 x10^9/L at baseline to 233 ± 109 x10^9/L after one week of therapy; this effect was maintained through 26 weeks (mean platelet count (± SD) at week 26: 254 ± 79 x10^9/L).

In aHUS Study 2, reduced signs of complement-mediated TMA activity, as shown by an increase in mean platelet counts from baseline to 26 weeks. In aHUS Study 2, mean platelet count (± SD) increased from 171 ± 83 x10^9/L to 233 ± 109 x10^9/L after one week of therapy; this effect was maintained through 26 weeks (mean platelet count (± SD) at week 26: 254 ± 79 x10^9/L).

In aHUS Study 2, reduced signs of complement-mediated TMA activity, as shown by an increase in mean platelet counts from baseline to 26 weeks. In aHUS Study 2, mean platelet count (± SD) increased from 171 ± 83 x10^9/L to 233 ± 109 x10^9/L after one week of therapy; this effect was maintained through 26 weeks (mean platelet count (± SD) at week 26: 254 ± 79 x10^9/L).

Table 12: Baseline Characteristics of Patients Enrolled in aHUS Study 2

<table>
<thead>
<tr>
<th>Parameter</th>
<th>aHUS Study 2 N = 20</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time from aHUS diagnosis until screening in months, median (min, max)</td>
<td>48 (0.66, 286)</td>
</tr>
<tr>
<td>Time from current clinical TMA manifestation until screening in months, median (min, max)</td>
<td>9 (1, 45)</td>
</tr>
<tr>
<td>Baseline LDH (U/L), median (range)</td>
<td>218 (105, 421)</td>
</tr>
<tr>
<td>Baseline eGFR (mL/min/1.73 m^2), median (range)</td>
<td>200 (151, 391)</td>
</tr>
</tbody>
</table>

Table 13: Efficacy Results for aHUS Study 2

<table>
<thead>
<tr>
<th>Efficacy Parameter</th>
<th>aHUS Study 2 at 26 wks</th>
<th>aHUS Study 2 at 2 yrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete TMA response, n (%)</td>
<td>N = 20</td>
<td>N = 20</td>
</tr>
<tr>
<td>eGFR improvement &gt;15 mL/min/1.73 m^2, n (%)</td>
<td>5 (25)</td>
<td>11 (55)</td>
</tr>
<tr>
<td>Median duration of complete TMA response, weeks (range)</td>
<td>32 (12, 38)</td>
<td>68 (38, 109)</td>
</tr>
<tr>
<td>Hematologic normalization, n (%)</td>
<td>1 (5)</td>
<td>6 (49)</td>
</tr>
<tr>
<td>Median duration of hematologic normalization, weeks (range)</td>
<td>16 (80)</td>
<td>19 (95)</td>
</tr>
<tr>
<td>Daily TMA intervention rate, median (range)</td>
<td>0.23 (0.0, 0.01)</td>
<td>0.23 (0.0, 0.01)</td>
</tr>
<tr>
<td>On eculizumab treatment</td>
<td>0.0 (0, 0.0)</td>
<td>0.0 (0, 0.01)</td>
</tr>
<tr>
<td>Before eculizumab</td>
<td>18 (90)</td>
<td>18 (90)</td>
</tr>
</tbody>
</table>

1 At data cut-off (September 8, 2010).
2 At data cut-off (April 20, 2012).
Patients in aHUS Study 5 received Soliris for a minimum of 26 weeks. In aHUS Study 5, the median duration of Soliris therapy was approximately 44 weeks (range: 1 dose to 88 weeks).

Recurrent function, as measured by gSF, was improved during Soliris therapy. The mean gSF (±SD) increased from 33 ± 30 mL/min/1.73m² at baseline to 89 ± 44 mL/min/1.73m² by 26 weeks. Among the 20 patients with a CKD stage ≥2 at baseline, 17 (85%) achieved a CKD improvement of ≥1 stage. Among the 16 patients ages 1 month to <12 years with a CKD stage ≥2 at baseline, 14 (88%) achieved a CKD improvement by ≥1 stage. Nine of the 11 patients who required dialysis at study baseline were able to discontinue dialysis during Soliris treatment. Responses were observed across all ages from 5 months to 17 years of age.

Reduction in terminal complement activity was observed in all patients after commencement of Soliris. Soliris reduced signs of complement-mediated TMA activity, as shown by an increase in mean platelet counts from baseline to week 26 (mean platelet count (±SD) at week 26: 293 ± 106 x10⁹/L). In aHUS Study 5, responses to Soliris were similar in patients with and without identified mutations in genes encoding complement regulatory factor proteins or auto-antibodies to factor H.

Table 18 summarizes the efficacy results for aHUS Study 5.

<table>
<thead>
<tr>
<th>Efficacy Parameter</th>
<th>Patients 1 month to &lt;12 years (N = 18)</th>
<th>All Patients (N = 22)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete TMA response, n (%)</td>
<td>11 (61)</td>
<td>14 (64)</td>
</tr>
<tr>
<td>95% CI</td>
<td>36, 83</td>
<td>41, 83</td>
</tr>
<tr>
<td>Median Duration of complete TMA response, weeks (range)</td>
<td>40 (14, 77)</td>
<td>37 (14, 77)</td>
</tr>
<tr>
<td>gSF improvement ≥15 mL/min/ 1.73m²/m² (n (%))</td>
<td>16 (89)</td>
<td>19 (86)</td>
</tr>
<tr>
<td>Median Duration of complete hematologic normalization, weeks (range)</td>
<td>14 (78)</td>
<td>18 (82)</td>
</tr>
<tr>
<td>Median Duration of complete hematologic normalization, weeks (range)</td>
<td>38 (14, 77)</td>
<td>38 (14, 77)</td>
</tr>
<tr>
<td>TMA Event-Free Status, n (%)</td>
<td>17 (84)</td>
<td>21 (95)</td>
</tr>
<tr>
<td>Daily TMA Intervention rate, median (range)</td>
<td>0.2 (0, 1.7)</td>
<td>0.4 (0, 1.7)</td>
</tr>
<tr>
<td>Before eculizumab treatment</td>
<td>0 (0, 0.01)</td>
<td>0 (0, 0.01)</td>
</tr>
<tr>
<td>After eculizumab treatment</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 18: Efficacy Results for aHUS Study 5

6 HOW SUPPLIED/STORAGE AND HANDLING

Soliris (eculizumab) is supplied as 300 mg single-dose vials containing 30 mL of 10 mg/mL sterile, preservative-free Soliris solution per vial.

Store Soliris vials in the original carton until time of use under refrigerated conditions at 2-8°C (36-46°F) and protected from light. Soliris vials may be held in the original carton at controlled room temperature (not more than 25°C/77°F) for only a single period up to 3 days. Do not use beyond the expiration date stamped on the carton. Refer to [Dosage and Administration (2)] for information on the stability and storage of diluted solutions of Soliris.

DO NOT FREEZE. DO NOT SHAKE.

NDC 25682-001-01 Single unit 300 mg carton: Contains one (1) 30 mL vial of Soliris (10 mg/mL).

17 PATIENT COUNSELING INFORMATION

Advises the patient to read FDA-approved patient labeling (Medication Guide).

Meningococcal Infection

Prior to treatment, patients should fully understand the risks and benefits of Soliris, in particular the risk of meningococcal infection. Ensure that patients receive the Medication Guide.

Inform patients that they are required to receive meningococcal vaccination at least 2 weeks prior to receiving the first dose of Soliris. If they have not previously been vaccinated, they are required to be revaccinated according to current medical guidelines. Inform patients that vaccination may not prevent meningococcal infection [see Warnings and Precautions (5.1)].

Signs and Symptoms of Meningococcal Infection

Inform patients about the signs and symptoms of meningococcal infection, and strongly advise patients to seek immediate medical attention if these signs or symptoms occur. Signs and symptoms are as follows:

- headache with nausea or vomiting
- headache and a fever
- headache with a stiff neck or stiff back
- fever
- fever and a rash
- confusion
- muscle aches with flu-like symptoms
- eyes sensitive to light

Inform patients that they will be given a Soliris Patient Safety Information Card that they should carry with them at all times. This card describes symptoms which, if experienced, should prompt the patient to immediately seek medical evaluation.

Other Infections

Inform patients that there may be an increased risk of other types of infections, particularly those due to encapsulated bacteria. Additionally, Aspergillus infections have occurred in immuno-compromised and neutropenic patients. Inform patients or caregivers of children receiving Soliris for the treatment of aHUS that their child should be vaccinated against Streptococcus pneumoniae and Haemophilus influenzae type b (Hib) according to current medical guidelines.

Discontinuation

Inform patients with PNH that they may develop hemolysis due to PNH when Soliris is discontinued and that they will be monitored by their healthcare professional for at least 8 weeks following Soliris discontinuation. Inform patients with aHUS that there is a potential for TMA complications due to aHUS when Soliris is discontinued and that they will be monitored by their healthcare professional for at least 12 weeks following Soliris discontinuation. Inform patients who discontinue Soliris to keep the Soliris Patient Safety Information Card with them for three months after the last Soliris dose, because the increased risk of meningococcal infection persists for several weeks following discontinuation of Soliris.

Manufactured by:
Alexion Pharmaceuticals, Inc.
100 College Street
New Haven, CT 06510 USA
US License Number 1743

This product, or its use, may be covered by one or more US patents, including US Patent No. 6,355,245 in addition to others including patents pending.
What is the most important information I should know about Soliris? Soliris is a medicine that affects your immune system. Soliris can lower the ability of your immune system to fight infections.

- Soliris increases your chance of getting serious and life-threatening meningococcal infections.

Meningococcal infections may quickly become life-threatening and cause death if not recognized and treated early.

1. You must receive meningococcal vaccination at least 2 weeks before your first dose of Soliris unless you have already had this vaccine. If your doctor decided that urgent treatment with Soliris is needed, you should receive meningococcal vaccination as soon as possible.

2. If you had a meningococcal vaccine in the past, you might need additional vaccination before starting Soliris. Your doctor will decide if you need additional meningococcal vaccination.

3. Meningococcal vaccines 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 a fever
   - headache with a stiff neck or stiff back
   - fever
   - fever and a rash
   - confusion
   - muscle aches with flu-like symptoms
   - eyes sensitive to light

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 3 months after your last Soliris dose. Stopping treatment with Soliris may cause breakdown of your red blood cells due to PNH. 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 doctor or nurse who treats you. This will help them diagnose and treat you quickly.

Soliris is only available through a program called the Soliris REMS. Before you can receive Soliris, your doctor must:

- enroll in the Soliris REMS program
- counsel you about the risk of meningococcal infection
- give you information about the symptoms of meningococcal infection
- give you a Patient Safety Card about your risk of meningococcal infection, as discussed above
- make sure that you are vaccinated with a meningococcal vaccine

Soliris may also increase the risk of other types of serious infections. If your child is treated with Soliris, make sure that your child receives vaccinations against Streptococcus pneumoniae and Haemophilus influenza type b (Hib).

What is Soliris? Soliris is a prescription medicine called a monoclonal antibody. Soliris is used to treat people with:

- a disease called Paroxysmal Nocturnal Hemoglobinuria (PNH). PNH affects red blood cells.
- A disease called atypical Hemolytic Uremic Syndrome (aHUS). aHUS affects the blood system, kidney, and sometimes other body organs.

Soliris works by blocking part of your immune system. This can help your symptoms but it can also increase your chance for infection.

It is important that you:

- have all recommended vaccinations before you start Soliris
- stay up-to-date with all recommended vaccinations during treatment with Soliris

Who Should Not Receive Soliris? Do not receive Soliris if you:

- have a meningococcal infection
- have not been vaccinated against meningitis infection unless your doctor decides that urgent treatment with Soliris is needed. See “What is the most important information I should know about Soliris?”

What should I tell my doctor before receiving Soliris? Before receiving Soliris, tell your doctor if you:

- have an infection or fever
- are pregnant or plan to become pregnant. It is not known if Soliris will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if Soliris passes into your breast milk.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Know the medications you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How will I receive Soliris? Soliris is given through a vein (I.V. or intravenous infusion) usually over 35 minutes in adults and 1-4 hours in pediatric patients. If you have an allergic reaction during your Soliris infusion, your doctor may decide to give Soliris more slowly or stop your infusion.

- If you are an adult, you will usually receive a Soliris infusion by your doctor:
  - weekly for five weeks, then
  - every 2 weeks
- If you are less than 18 years of age, your doctor will decide how often you will receive Soliris depending on your age and body weight
- After each infusion, you should be monitored for one hour for allergic reactions. See “What are the possible side effects of Soliris?”
- If you forget or miss a Soliris infusion, call your doctor right away.
- If you have PNH, your doctor 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
- chest pain
- kidney problems
- blood clots
- difficulty breathing
- if you have aHUS, your doctor will need to monitor you closely during and for at least 12 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 with abnormal clotting may include:

- stroke
- confusion
- seizures
- chest pain (angina)
- difficulty breathing
- kidney problems
- swelling in arms or legs
- a drop in your platelet count

What are the possible side effects of Soliris? Soliris can cause serious side effects including:

- See “What is the most important information I should know about Soliris?”
• Serious allergic reactions. Serious allergic reactions can happen during your Soliris infusion. Tell your doctor 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
  ◦ feel faint or pass out

If you have an allergic reaction to Soliris, your doctor may need to infuse Soliris more slowly, or stop Soliris. See “How will I receive Soliris?”

Common side effects in people with PNH treated with Soliris include:
• headaches
• runny nose and colds
• sore throat
• back pain
• nausea

Common side effects in people with aHUS treated with Soliris include:
• headache
• diarrhea
• hypertension
• common cold (upper respiratory infection)
• abdominal pain
• vomiting
• nasopharyngitis
• anemia
• cough
• peripheral edema
• nausea
• urinary tract infections
• pyrexia

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 Soliris. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about Soliris
Medicines are sometimes prescribed for conditions other than those listed in a Medication Guide. This Medication Guide summarizes the most important information about Soliris. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Soliris that is written for healthcare professionals.

What are the ingredients in Soliris?
Active ingredient: eculizumab
Inactive ingredients: sodium phosphate monobasic, sodium phosphate dibasic, sodium chloride, polysorbate 80 (vegetable origin) and Water for Injection

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Manufactured by Alexion Pharmaceuticals, Inc., 100 College Street, New Haven, CT 06510 USA.

Revised: 01/2017