In pediatric patients with aHUS, INHIBIT complement-mediated thrombotic microangiopathy (TMA) with Soliris®

Indications and Usage
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).

Please see pages 16-17 for Important Safety Information.
Please see accompanying full prescribing information for Soliris, including boxed WARNING regarding serious meningococcal infection.
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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

WARNING: SERIOUS MENINGOCOCCAL INFECTIONS
See full prescribing information for complete boxed warning
Life-threatening and fatal meningococcal infections have occurred in patients treated with Soliris and may become rapidly life-threatening or fatal if not recognized and treated early.

• Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccination in patients with complement deficiencies.
• Immunize patients with a meningococcal vaccine at least 2 weeks prior to administering the first dose of Soliris, unless the risks of delaying Soliris therapy outweigh the risks of developing a meningococcal infection. (See Serious Meningococcal Infections for additional guidance on the management of the risk of meningococcal infection.)
• Monitor patients for early signs of meningococcal infections, and evaluate immediately if infection is suspected.
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.
Soliris® specifically inhibits chronic, uncontrolled complement activity, which causes the signs and clinical manifestations of aHUS\textsuperscript{1-6}

Soliris binds C5 to block terminal complement activity\textsuperscript{1,5,7,8}

- Immune response of the proximal pathway remains intact\textsuperscript{8}

Please see pages 16-17 for Important Safety Information.
Please see accompanying full prescribing information for Soliris, including boxed WARNING regarding serious meningococcal infection.
First prospective clinical trial of Soliris® in pediatric patients with aHUS

• Open-label, single-arm, multicenter, multinational clinical trial

Study design

Inclusion Criteria
• Age 1 month to <18 years with a body weight ≥5 kg
• Platelet count < Lower limit of normal range (LLN)
• Signs or symptoms of hemolysis
  — LDH ≥1.5 x Upper limit of normal range (ULN)
  — Hemoglobin ≤ LLN
  — Fragmented red blood cells with a negative Coombs test
• Serum creatinine (SCr) ≥97th percentile for age without the need for chronic dialysis
• No requirement for identified complement mutation or antibody
• ADAMTS13 activity >5%

Exclusion Criteria
• Chronic dialysis
• Shiga toxin–producing E. coli (STEC-HUS) infection
• Plasma exchange/plasma infusion (PE/PI) for >5 weeks prior to enrollment

Primary endpoint
• Proportion of patients who achieved complete TMA response during 26 weeks*

Secondary endpoints
• Safety and tolerability
• Hematologic normalization†
• TMA event-free status
• Recovery of kidney function‡
• Change in health-related quality of life
• Elimination of PE/PI and dialysis

*Complete TMA response defined as platelet count ≥150 x 10^9/L, lactate dehydrogenase (LDH) < upper limit of normal (ULN), and ≥25% improvement in SCr from baseline. All 3 parameters had to be met on 2 consecutive measurements obtained ≥4 weeks apart.
†Hematologic normalization defined as platelet count ≥150 x 10^9/L and LDH < ULN sustained for ≥2 consecutive measurements obtained ≥4 weeks apart.
‡Measured by increase from baseline in estimated glomerular filtration rate (eGFR), changes from baseline in serum creatinine (SCr), and improvement ≥1 stage from baseline in chronic kidney disease (CKD). eGFR was calculated using the Schwartz formula: eGFR (mL/min/1.73 m²)=[0.413 x height (cm)]/SCr (mg/dL).
Patients exhibited a broad range of baseline characteristics

Demographics and baseline laboratory values*

<table>
<thead>
<tr>
<th>Category</th>
<th>Intent-to-treat population (N=22)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients ranged in age from 5 months to 18 years†</td>
<td></td>
</tr>
<tr>
<td>1 month to &lt;23 months, n (%)</td>
<td>5 (22.7)</td>
</tr>
<tr>
<td>≥23 months to &lt;5 years, n (%)</td>
<td>5 (22.7)</td>
</tr>
<tr>
<td>≥5 to &lt;12 years, n (%)</td>
<td>8 (36.4)</td>
</tr>
<tr>
<td>≥12 to &lt;18 years, n (%)</td>
<td>4 (18.2)</td>
</tr>
<tr>
<td>The majority of patients were newly diagnosed</td>
<td></td>
</tr>
<tr>
<td>First clinical TMA manifestation, n (%)</td>
<td>16 (73)</td>
</tr>
<tr>
<td>50% of patients did not have an identified genetic mutation</td>
<td>11 (50)</td>
</tr>
<tr>
<td>55% of patients did not receive PE/PI during current manifestation, n (%)</td>
<td>12 (55)</td>
</tr>
<tr>
<td>Patients showed evidence of disease severity</td>
<td></td>
</tr>
<tr>
<td>Platelet count &lt;150 x 10⁹/L, n (%)</td>
<td>22 (100)</td>
</tr>
<tr>
<td>eGFR (mL/min/1.73 m²), mean (SD)</td>
<td>33 (30.37)</td>
</tr>
<tr>
<td>Dialysis at baseline, n (%)†</td>
<td>11 (50)</td>
</tr>
<tr>
<td>Prior renal transplant, n (%)</td>
<td>2 (9)</td>
</tr>
</tbody>
</table>

*One patient who was on dialysis at baseline discontinued dialysis during the baseline window prior to the first dose of Soliris.

†Patients as young as 1 month old were eligible for study inclusion.

eGFR = estimated glomerular filtration rate. PE/PI = plasma exchange/plasma infusion. SD = standard deviation.

- Median duration (range) from the onset of the presenting clinical manifestation to first dose was 6 days (1 day to 4 months)†,9
- 19 patients completed the 26-week study period9
  — Of the 3 patients who withdrew, 1 patient was diagnosed with STEC-HUS, 1 patient had a serious adverse event (agitation), and 1 patient’s family requested to withdraw9

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.

**Please see pages 16-17 for Important Safety Information.**

Please see accompanying full prescribing information for Soliris, including boxed WARNING regarding serious meningococcal infection.
Treatment with Soliris® resulted in complete TMA response in 64% (14/22) of pediatric patients with aHUS.*1,9

- Complete TMA response was defined by a combination of renal and hematological endpoints1,9
  — Median time to complete TMA response was 60 (7-153) days9

Proportion of patients achieving platelet count and LDH normalization at 26 weeks†‡9

<table>
<thead>
<tr>
<th></th>
<th>Proportion of patients (%)</th>
<th>Platelet count normalization</th>
<th>LDH normalization</th>
</tr>
</thead>
</table>
| *Complete TMA response defined as platelet count ≥150 x 10⁹/L, LDH < upper limit of normal (ULN), and ≥25% improvement in serum creatinine from baseline. All 3 parameters had to be met on 2 consecutive measurements obtained ≥4 weeks apart.† Platelet count normalization defined as ≥150 x 10⁹/L for ≥2 consecutive measurements obtained ≥4 weeks apart.‡ LDH normalization defined as LDH < ULN sustained for ≥2 consecutive measurements obtained ≥2 weeks apart.§ Hematologic normalization defined as platelet count ≥150 x 10⁹/L and LDH < ULN sustained for ≥2 consecutive measurements obtained ≥4 weeks apart.

82% of patients achieved hematologic normalization11,9

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Mean improvement in platelet count from baseline was 205 x 10⁹/L¹

Mean platelet count improvement*²

- All patients had low platelet counts at baseline, characteristic of aHUS (<150 x 10⁹/L) with a mean platelet count ± SD of 88 ± 42 x 10⁹/L¹,⁹
- Median time (range) to platelet count normalization was 7 (1-80) days⁹
- Of the 10 patients receiving PE/PI at baseline, none required PE/PI by the end of the 26-week study period⁹

Improvements in platelet count were rapid and sustained¹,⁹

* Bars represent standard error of the mean.

‡ Platelet count normalization defined as ≥150 x 10⁹/L for ≥2 consecutive measurements obtained ≥4 weeks apart.

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, pyrexia.

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Mean increase in eGFR from baseline was 65 mL/min/1.73 m²

Mean improvement in eGFR

86% (19/22) of patients achieved improvement in renal function

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Dialysis was eliminated in 82% of pediatric patients with aHUS at 26 weeks\textsuperscript{1,9}

- Dialysis was eliminated in 9/11 pediatric patients receiving dialysis at study entry\textsuperscript{1,9}
  - All patients not on dialysis at start of treatment remained dialysis free\textsuperscript{9}

In the pediatric study, 85% (17/20) of patients with CKD stage $\geq 2$ at baseline achieved improvement of $\geq 1$ stage within 26 weeks\textsuperscript{1}

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

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### Per patient incidence of adverse reactions in 10% or more patients enrolled in aHUS Study 5

<table>
<thead>
<tr>
<th>Category</th>
<th>Number (% of patients)</th>
<th>1 month to &lt;12 years (n=18)</th>
<th>Total (n=22)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Eye disorders</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eye disorders</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>6 (33)</td>
<td>7 (32)</td>
<td></td>
</tr>
<tr>
<td>Diarrhea</td>
<td>5 (28)</td>
<td>7 (32)</td>
<td></td>
</tr>
<tr>
<td>Vomiting</td>
<td>4 (22)</td>
<td>6 (27)</td>
<td></td>
</tr>
<tr>
<td>Dyspepsia</td>
<td>0</td>
<td>3 (14)</td>
<td></td>
</tr>
<tr>
<td>General disorders and administration site conditions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pyrexia</td>
<td>9 (50)</td>
<td>11 (50)</td>
<td></td>
</tr>
<tr>
<td>Infections and Infestations</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>5 (28)</td>
<td>7 (32)</td>
<td></td>
</tr>
<tr>
<td>Nasopharyngitis</td>
<td>3 (17)</td>
<td>6 (27)</td>
<td></td>
</tr>
<tr>
<td>Rhinitis</td>
<td>4 (22)</td>
<td>4 (18)</td>
<td></td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>3 (17)</td>
<td>4 (18)</td>
<td></td>
</tr>
<tr>
<td>Catheter site infection</td>
<td>3 (17)</td>
<td>3 (14)</td>
<td></td>
</tr>
<tr>
<td>Musculoskeletal and Connective Tissue Disorders</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Muscle spasms</td>
<td>2 (11)</td>
<td>3 (14)</td>
<td></td>
</tr>
<tr>
<td>Nervous System Disorders</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td>3 (17)</td>
<td>4 (18)</td>
<td></td>
</tr>
<tr>
<td>Renal and Urinary Disorders</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td>3 (17)</td>
<td>4 (18)</td>
<td></td>
</tr>
<tr>
<td>Respiratory, Thoracic and Mediastinal Disorders</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cough</td>
<td>7 (39)</td>
<td>8 (36)</td>
<td></td>
</tr>
<tr>
<td>Oropharyngeal pain</td>
<td>1 (6)</td>
<td>3 (14)</td>
<td></td>
</tr>
<tr>
<td>Skin and Subcutaneous Tissue Disorders</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rash</td>
<td>4 (22)</td>
<td>4 (18)</td>
<td></td>
</tr>
<tr>
<td>Vascular Disorders</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>4 (22)</td>
<td>4 (18)</td>
<td></td>
</tr>
</tbody>
</table>

- No deaths or meningococcal infections reported during the study period
- Majority of serious adverse events were mild to moderate in severity

**WARNING: SERIOUS MENINGOCOCCAL INFECTIONS**

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Life-threatening and fatal meningococcal infections have occurred in patients treated with Soliris and may become rapidly life-threatening or fatal if not recognized and treated early.

- Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccination in patients with complement deficiencies.
- Immunize patients with a meningococcal vaccine at least 2 weeks prior to administering the first dose of Soliris, unless the risks of delaying Soliris therapy outweigh the risks of developing a meningococcal infection. (See *Serious Meningococcal Infections* for additional guidance on the management of the risk of meningococcal infection.)
- Monitor patients for early signs of meningococcal infections, and evaluate immediately if infection is suspected.

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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, pyrexia.

Patients who discontinue or deviate from the recommended dosing schedule of Soliris® are at immediate and ongoing risk of severe complications from TMA\(^1,3\)

- Monitor patients for signs and symptoms of TMA complications\(^1\)

In the aHUS pivotal program (N=67), 5/18 adult and pediatric patients who discontinued Soliris treatment experienced severe complications from TMA\(^1,3\)

- Patients who continued treatment had complete inhibition of complement activity sustained through 2 years\(^1,3\)
- Of the patients who experienced severe complications from TMA:
  - 40% (2/5) were pediatric patients\(^10\)
  - 80% (4/5) reinitiated Soliris treatment\(^11,3\)

**Clinical signs and symptoms of TMA after discontinuation may include:**
- Change in mental status
- Angina
- Thrombosis
- Dyspnea
- Seizures

**Laboratory signs of TMA after discontinuation include (any 2, or repeated measures of 1):**
- Decreased platelets
- Increased LDH
- Increased serum creatinine

**In patients who discontinue Soliris, clinical and laboratory signs should be monitored for at least 12 weeks\(^1\)**

**If TMA complications occur after Soliris discontinuation, consider reinstitution of Soliris treatment, plasma therapy (plasmapheresis, plasma exchange, or fresh frozen plasma infusion [PE/PI]), or appropriate organ-specific supportive measures\(^1\)**

\(* 18\) patients included 5 patients (1 pediatric patient <18 years of age) from Study 1 and Study 2 prospective trials and 13 patients (6 pediatric patients <18 years of age) from the Study 3 retrospective trial.

\(†\) Included 1 pediatric patient from the Study 2 prospective trial and 1 pediatric patient from the Study 3 retrospective trial.

\(‡\) Both pediatric patients who experienced severe TMA complications upon discontinuation reinitiated Soliris treatment.

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, pyrexia.

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Soliris® is approved for use in pediatric patients with aHUS*1

- Soliris should be administered at the recommended dosage regimen time points, or within 2 days of these time points1
- IV infusion over 1 to 4 hours1

### aHUS weight-based dosing schedule for patients <18 years1

<table>
<thead>
<tr>
<th>Body Weight</th>
<th>Induction Phase</th>
<th>Maintenance Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Week</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Infusion</td>
<td>1200 mg</td>
</tr>
<tr>
<td>40 kg and over</td>
<td>1</td>
<td>900 mg</td>
</tr>
<tr>
<td>30 kg to less than 40 kg</td>
<td>2</td>
<td>900 mg</td>
</tr>
<tr>
<td>20 kg to less than 30 kg</td>
<td>3</td>
<td>600 mg</td>
</tr>
<tr>
<td>10 kg to less than 20 kg</td>
<td>4</td>
<td>600 mg</td>
</tr>
<tr>
<td>5 kg to less than 10 kg</td>
<td>5</td>
<td>300 mg</td>
</tr>
</tbody>
</table>

Immune patients without a history of meningococcal vaccination at least 2 weeks prior to receiving the first dose of Soliris1

- If urgent Soliris therapy is indicated in an unvaccinated patient, administer the meningococcal vaccine as soon as possible1
- Administer a polyvalent meningococcal vaccine according to the most current Advisory Committee on Immunization Practices (ACIP) recommendations for patients with complement deficiencies1
- Closely monitor patients for early signs and symptoms of meningococcal infection and evaluate patients immediately if an infection is suspected1

Children treated with Soliris may be at increased risk of developing serious infections due to *Streptococcus pneumoniae* and *Haemophilus influenzae* type b (Hib)1

- Administer vaccinations for the prevention of these according to ACIP guidelines

*Physicians must read Important Safety Information prior to administering Soliris.

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Alexion's goal is to ensure that all patients with aHUS who may benefit from Soliris® will have access to it.

An Alexion Nurse Case Manager, all of whom are registered nurses and all of whom have extensive insurance and clinical experience, will be assigned to each patient and his or her healthcare team. Nurse Case Managers have a wealth of information (in multiple languages) on:

**Education**
- Collaborating with you and your patient, reinforcing your patient’s knowledge, and providing educational resources related to aHUS and Soliris
- Providing preinfusion information to patients to establish expectations
- Helping answer patients' questions about treatment with Soliris

**Assistance with coverage issues and funding options**
- Helping patients and your office staff navigate insurance issues and coordinate special patient needs (ie, providing information on insurance verifications, coverage determinations, and, if necessary, assistance in researching alternative funding options)

**Treatment support**
- Assisting with solutions for maintaining therapy during major life events, such as a change in family, job, provider, or insurance status
- Investigating home infusion options
- Helping find alternative infusion centers if a patient is traveling
- Simplifying ordering and distribution

Contact OneSource™ at 1.888.SOLIRIS (1.888.765.4747)

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Soliris® Important Safety Information

Indications and Usage

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**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).

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

Warnings and Precautions

**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 influenzae* type b (Hib). Administer vaccinations for the prevention of *Streptococcus pneumoniae* and *Haemophilus influenzae* type b (Hib) infections according to ACIP guidelines. Use caution when administering Soliris to patients with any systemic infection.

**Monitoring Disease Manifestations After Soliris Discontinuation**
**Treatment Discontinuation for PNH**
Monitor patients after discontinuing Soliris for at least 8 weeks to detect hemolysis.

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Soliris® Important Safety Information

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 two, 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 reinstitution of Soliris treatment, plasma therapy [plasmapheresis, plasma exchange, or fresh frozen plasma infusion (PE/PI)], or appropriate organ-specific supportive measures.

Infusion Reactions
As with all protein products, administration of Soliris may result in infusion reactions, including anaphylaxis or other hypersensitivity reactions. In clinical trials, no patients experienced an infusion reaction which required discontinuation of Soliris. Interrupt Soliris infusion and institute appropriate supportive measures if signs of cardiovascular instability or respiratory compromise occur.

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.

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. 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, pyrexia.

Please see accompanying full prescribing information for Soliris, including boxed WARNING regarding serious meningococcal infection.
A clinical trial in pediatric patients with aHUS has shown that early intervention with Soliris is associated with rapid improvement in hematological markers and continued improvement of kidney function.

Soliris eliminated the need for PE/PI in 100% of pediatric patients on PE/PI at baseline.

82% of pediatric patients who were on dialysis at initiation of Soliris no longer required dialysis.

The most commonly reported serious adverse events in the Soliris pediatric study were hypertension (9%), viral gastroenteritis (9%), pyrexia (9%), and upper respiratory infection (9%).

Soliris is an effective treatment for pediatric patients with aHUS.

For more information, call OneSource™ at 1.888.SOLIRIS (1.888.765.4747)

WARNING: SERIOUS MENINGOCOCCAL INFECTIONS

See full prescribing information for complete boxed warning

Life-threatening and fatal meningococcal infections have occurred in patients treated with Soliris and may become rapidly life-threatening or fatal if not recognized and treated early.

- Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccination in patients with complement deficiencies.
- Immunize patients with a meningococcal vaccine at least 2 weeks prior to administering the first dose of Soliris, unless the risks of delaying Soliris therapy outweigh the risks of developing a meningococcal infection. (See Serious Meningococcal Infections for additional guidance on the management of the risk of meningococcal infection.)
- Monitor patients for early signs of meningococcal infections, and evaluate immediately if infection is suspected.

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.

Please see pages 16-17 for Important Safety Information.
Please see accompanying full prescribing information for Soliris, including boxed WARNING regarding serious meningococcal infection.