ULTOMIRIS®
(ravulizumab-cwvz)
injection for intravenous use
300 mg/3 mL vial

WIDEN THEIR WORLD

INFUSE YOUR ATYPICAL-HUS PATIENTS WITH UP TO 8 WEEKS OF FREEDOM[1,a]

[a]Starting 2 weeks after the loading dose, maintenance doses are administered once every 4 or 8 weeks (depending on body weight).

INDICATION

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

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

Subcutaneous Adult Patients with aHUS
Subcutaneous administration of ULTOMIRIS is not approved for use in pediatric patients.

SELECT IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS MENINGOCOCCAL INFECTIONS

Life-threatening meningococcal infections/sepsis have occurred in patients treated with ULTOMIRIS. Meningococcal infection 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 meningococcal vaccines at least 2 weeks prior to administering the first dose of ULTOMIRIS, unless the risks of delaying ULTOMIRIS therapy outweigh the risk of developing a meningococcal infection. See *Warnings and Precautions* for additional guidance on the management of the risk of meningococcal infection.**
- **Vaccination reduces, but does not eliminate, the risk of meningococcal infections. Monitor patients for early signs of 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 REMS.

Please see accompanying full Prescribing Information, including Boxed WARNING regarding serious and life-threatening meningococcal infections/sepsis enclosed in the pocket. Please see additional Important Safety Information on inside flap.

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SELECT IMPORTANT SAFETY INFORMATION (continued)

CONTRAINDICATIONS

- Patients with unresolved *Neisseria meningitidis* infection.
- Patients who are not currently vaccinated against *Neisseria meningitidis*, unless the risks of delaying ULTOMIRIS treatment outweigh the risks of developing a meningococcal infection.

WARNINGS AND PRECAUTIONS

Serious Meningococcal Infections
Life-threatening meningococcal infections have occurred in patients treated with ULTOMIRIS. The use of ULTOMIRIS increases a patient's susceptibility to serious meningococcal infections (septicemia and/or meningitis). Meningococcal disease due to any serogroup may occur.

Vaccinate or revaccinate for meningococcal disease according to the most current ACIP recommendations for patients with complement deficiencies. Immunize patients without history of meningococcal vaccination at least 2 weeks prior to the first dose of ULTOMIRIS. Patients who initiate ULTOMIRIS treatment less than 2 weeks after receiving meningococcal vaccine(s) must receive appropriate prophylactic antibiotics until 2 weeks after vaccination.

The benefits and risks of antibiotic prophylaxis for prevention of meningococcal infections in patients receiving ULTOMIRIS have not been established. Consider discontinuation of ULTOMIRIS in patients who are undergoing treatment for serious meningococcal infection.

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

Under the ULTOMIRIS REMS, prescribers must enroll in the program. Prescribers must counsel patients about the risk of meningococcal infection/sepsis, provide the patients with the REMS educational materials, and ensure patients are vaccinated with meningococcal vaccines.

Additional information on the REMS requirements is available at www.ultomirisrems.com or 1-888-765-4747.

Other Infections
Patients may have increased susceptibility to infections, especially with encapsulated bacteria, such as infections caused by *Neisseria meningitidis* but also *Streptococcus pneumoniae*, *Haemophilus influenzae*, and to a lesser extent, *Neisseria gonorrhoeae*. Children treated with ULTOMIRIS may be at increased risk of developing serious infections due to *Streptococcus pneumoniae* and *Haemophilus influenzae* type b (Hib). Administer vaccinations for the prevention of *Streptococcus pneumoniae* and *Haemophilus influenzae* type b (Hib) infections according to ACIP guidelines. If ULTOMIRIS is administered to patients with active systemic infections, monitor closely for worsening infection.

Monitoring Disease Manifestations after ULTOMIRIS Discontinuation
ULTOMIRIS treatment of aHUS should be a minimum duration of 6 months. Due to heterogeneous nature of aHUS events and patient-specific risk factors, treatment duration beyond the initial 6 months should be individualized. There are no specific data on ULTOMIRIS discontinuation. After discontinuing treatment with ULTOMIRIS, patients should be monitored for clinical symptoms and laboratory signs of TMA complications for at least 12 months.

TMA complications post-discontinuation can be identified if any of the following is observed: Clinical symptoms of TMA include changes in mental status, seizures, angina, dyspnea, thrombosis or increasing blood pressure.

SELECT IMPORTANT SAFETY INFORMATION (continued)

Monitoring Disease Manifestations after ULTOMIRIS Discontinuation (continued)
In addition, at least two of the following laboratory signs observed concurrently and results should be confirmed by a second measurement 28 days apart with no interruption: a decrease in platelet count of 25% or more as compared to either baseline or to peak platelet count during ULTOMIRIS treatment; an increase in serum creatinine of 25% or more as compared to baseline or to nadir during ULTOMIRIS treatment; or, an increase in serum LDH of 25% or more as compared to baseline or to nadir during ULTOMIRIS treatment. If TMA complications occur after discontinuation, consider reinitiation of ULTOMIRIS treatment or appropriate organ-specific supportive measures.

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

Infusion-Related Reactions
Intravenous or subcutaneous 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% of patients treated with ULTOMIRIS. These events included lower back pain, drop in blood pressure, elevation in blood pressure, limb discomfort, drug hypersensitivity (allergic reaction), dysgeusia (bad taste), and drowsiness. These reactions did not require discontinuation of ULTOMIRIS. If signs of cardiovascular instability or respiratory compromise occur, interrupt ULTOMIRIS infusion and institute appropriate supportive measures.

Injection Site Reactions- Subcutaneous administration
27% (23/84) of patients treated with subcutaneous administration of ULTOMIRIS experienced injection site reactions which included application site rash, device allergy, infusion site pain, infusion site reaction, injection site bruising, injection site erythema, injection site hematoma, injection site induration, injection site inflammation, injection site pain, injection site pruritus, injection site rash, injection site reaction, injection site swelling, injection site urticaria, medical device site bruise, medical device site erythema, medical device site hematoma, medical device site induration, medical device site pruritus, medical device site rash, and medical device site reaction.

Allergies to Acrylic Adhesives
The on-body injector of ULTOMIRIS uses acrylic adhesive. For patients with a known allergy to acrylic adhesive, use of this product may result in an allergic reaction. Premedication can be considered, and supportive measures should be instituted if signs of allergy appear.

ADVERSE REACTIONS
Most common adverse reactions in patients with aHUS (incidence ≥20%) were upper respiratory tract infection, diarrhea, nausea, vomiting, headache, hypertension and pyrexia. Serious adverse reactions were reported in 42 (57%) patients with aHUS receiving ULTOMIRIS. The most frequent serious adverse reactions reported in more than 2 patients (2.7%) treated with ULTOMIRIS were hypertension, pneumonia and abdominal pain. In clinical studies, clinically relevant adverse reactions in <10% of patients include viral tonsillitis in adults and viral infection in pediatric patients and in 3% of adult patients include infusion-related reactions.

Adverse Reactions for Subcutaneous Administration of ULTOMIRIS
Most common adverse reactions (≥10%) with ULTOMIRIS subcutaneous administration via On Body Injector in adult patients with PNH were local injection site reactions, diarrhea, and headache.

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.

ULTOMIRIS IS THE FIRST AND ONLY LONG-ACTING COMPLEMENT INHIBITOR FOR ATYPICAL-HUS

IMMEDIATE
100% (n=70) of adult and pediatric patients
had complete C5 inhibition after the first infusion of ULTOMIRIS.

COMPLETE
54% (30/56; CI: 40-67%) of adult and 71% (10/14; CI: 42-92%) of pediatric patients
met the composite endpoint of complete TMA response[a] with ULTOMIRIS by 26 weeks.

SUSTAINED
Up to 8 weeks of sustained C5 inhibition and the possibility to live dialysis-free in adult and pediatric patients

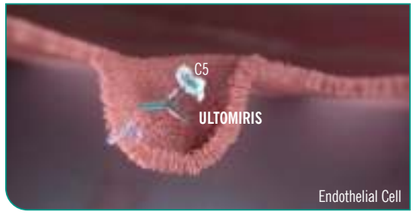
ULTOMIRIS IS DOSED BASED ON WEIGHT[1]	ULTOMIRIS TREATMENT DURATION MAY BE INDIVIDUALIZED[1]
Starting 2 weeks after the loading dose, ULTOMIRIS maintenance doses are administered once every 4 or 8 weeks (depending on body weight)	ULTOMIRIS treatment of atypical-HUS should be a minimum duration of 6 months • Due to the heterogeneous nature of atypical-HUS events and patient-specific risk factors, treatment duration beyond the initial 6 months should be individualized • If the patient discontinues treatment with ULTOMIRIS, patients should be monitored for clinical symptoms and laboratory signs of TMA complications for at least 12 months • There are no specific data on ULTOMIRIS discontinuation

Please see the Prescribing Information for additional information on dosing and treatment duration.

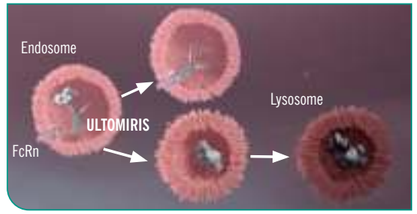
[a]Complete TMA response was defined as normalization of hematological parameters (platelet count and LDH) and ≥25% improvement in serum creatinine from baseline during the 26-week initial evaluation period. Patients had to meet all criteria at 2 separate assessments obtained at least 4 weeks (28 days) apart and any measurement in between.
CI=confidence interval; defined as 95%; LDH=lactate dehydrogenase.

ULTOMIRIS, BUILT ON THE FOUNDATION OF ECULIZUMAB, HAS AN ~4X LONGER HALF LIFE[a,b]

1
Both **ULTOMIRIS** and eculizumab bind to C5 in the bloodstream to prevent its activation.[1,2]

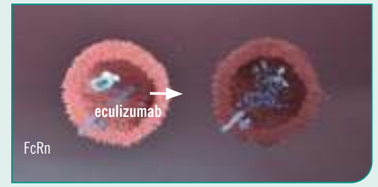


2
ULTOMIRIS is engineered to release C5 in the endosome as pH levels drop and use FcRn to recycle back to the bloodstream, leaving C5 to be degraded by the lysosome.[3]



3
ULTOMIRIS has also been engineered to bind to FcRn with greater affinity with a half-life ~4x longer than eculizumab to provide immediate, complete, and sustained inhibition of C5 for up to 8 weeks.[2,3,c]

ULTOMIRIS differs from eculizumab in how it behaves after binding to C5. For eculizumab, binding to C5 inhibits FcRn-mediated recycling, leading to its lysosomal degradation along with C5.[3]



[a]The mean (%CV) terminal elimination half-life and clearance of ULTOMIRIS in patients with atypical-HUS are 51.8 (31.3) days and 0.08 (53.3) L/day, respectively. Half-life of eculizumab is 11.25 to 17.25 days.[1,2]
[b]Targeted engineering to incorporate 4 amino acid substitutions designed to reduce TMDD and enhance FcRn-mediated recycling into eculizumab has led to the generation of ULTOMIRIS, which exhibited an extended duration of action in preclinical models relative to eculizumab.[3]
[c]In the majority (93%) of adult and pediatric patients with atypical-HUS throughout the entire 26-week treatment period.[1]
%CV=coefficient of variation; FcRn=human neonatal Fc receptor; TMDD=target-mediated drug disposition.

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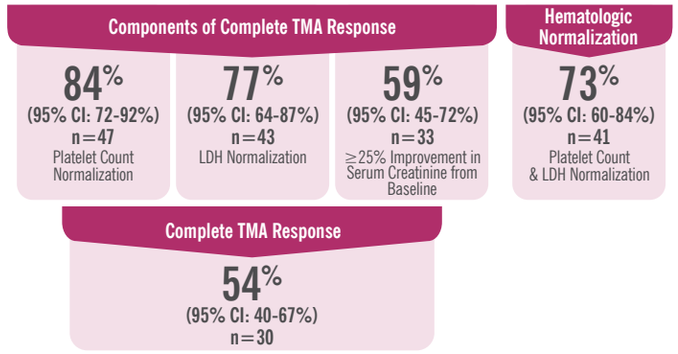
IMMEDIATE C5 inhibition was observed on day 1 in adult patients[4]

100% (56/56) of adult patients in a 26-week study demonstrated complete C5 inhibition after the first infusion of ULTOMIRIS[4,a]

COMPLETE TMA response was achieved in the majority of adult patients taking ULTOMIRIS in a 26-week study[1]



- **100% (30/30)** of complete TMA responses were maintained through all available follow-up in adult patients[1,b]
- **>99.5%** of all free C5 serum samples in adult patients showed complete inhibition of C5 throughout the 6-month study period with ULTOMIRIS[4,a]

SUSTAINED C5 inhibition and an opportunity to discontinue dialysis in adult patients[1]

8 weeks of sustained C5 inhibition in adult patients[1]

At 26 weeks:

An opportunity for your adult patients to discontinue dialysis

- 17 of the 29 patients (59%) who required dialysis at study entry discontinued dialysis by the end of available follow-up[1,b]
- 6 of 27 patients who were off dialysis at baseline were on dialysis at last available follow-up[1,b]

Potential for recovery of kidney function in your adult patients

- Mean eGFR was 51.8 mL/min/1.73 m^2 at end of study, a 35.9 mL/min/1.73 m^2 (227%) mean increase from baseline[1,b]

Adult Study Design

- 26-week, open-label, single-arm study of 56 adult patients who displayed signs of TMA and were naive to complement inhibitor treatment[1]
- Inclusion: platelet count ≤150 x 10^9/L, evidence of hemolysis such as an elevation in serum LDH, and serum creatinine above the upper limits of normal or required dialysis[1]
- Exclusion: patients with TMA due to ADAMTS13 deficiency, STEC-HUS, and genetic defect in cobalamin C metabolism[1]
- Primary end point: complete TMA response,[c] which comprised: platelet count normalization (≥150 × 10^9/L), serum LDH normalization (≤246 U/L), and ≥25% improvement in serum creatinine from baseline[1,4]
- Select secondary end points: time to complete TMA response and complete TMA response status over time, dialysis requirement and CKD stage as evaluated by eGFR, hemoglobin response, and change from baseline in quality of life[4]

Please see the Prescribing Information for demographics and baseline characteristics of patients in Study 311.

[a]As measured by free C5 serum concentration of <0.5 mcg/mL.[1]
[b]Secondary end point.[4]
[c]Complete TMA response was defined as normalization of hematological parameters (platelet count and LDH) and ≥25% improvement in serum creatinine from baseline during the 26-week initial evaluation period. Patients had to meet all criteria at 2 separate assessments obtained at least 4 weeks (28 days) apart and any measurement in between.[1]

ADAMTS13=a disintegrin and metalloproteinase with a thrombospondin type 1 motif member 13; CKD=chronic kidney disease; eGFR=estimated glomerular filtration rate.

Adverse Reactions Reported in ≥10% of ULTOMIRIS-Treated Adult Patients With Atypical-HUS[1]

BODY SYSTEM ADVERSE REACTION	ADULT PATIENTS (N=58) All Grades*** (n=53) n (%)	ADULT PATIENTS (N=58) ≥ Grade 3 (n=14) n (%)
Blood and lymphatic system disorders		
Anemia	8 (14)	0 (0)
Gastrointestinal disorders		
Diarrhea	18 (31)	2 (3)
Nausea	15 (26)	2 (3)
Vomiting	15 (26)	2 (3)
Constipation	8 (14)	1 (2)
Abdominal pain	7 (12)	1 (2)
General disorders and administration site conditions		
Pyrexia	11 (19)	1 (2)
Edema peripheral	10 (17)	0 (0)
Fatigue	8 (14)	0 (0)
Infections and infestations		
Upper respiratory tract infection*	15 (26)	0 (0)
Urinary tract infection	10 (17)	5 (9)
Gastrointestinal infection**	8 (14)	2 (3)
Metabolism and nutrition disorders		
Hypokalemia	6 (10)	1 (2)
Musculoskeletal and connective tissue disorders		
Arthralgia	13 (22)	0 (0)
Back pain	7 (12)	1 (2)
Muscle spasms	6 (10)	0 (0)
Pain in extremity	6 (10)	0 (0)
Nervous system disorders		
Headache	23 (40)	1 (2)
Psychiatric disorders		
Anxiety	8 (14)	1 (2)
Respiratory, thoracic, and mediastinal disorders		
Cough	10 (17)	0 (0)
Dyspnea	10 (17)	1 (2)
Skin and subcutaneous tissue disorders		
Alopecia	6 (10)	0 (0)
Dry skin	6 (10)	0 (0)
Vascular disorders		
Hypertension	14 (24)	7 (12)

The most frequent adverse reactions reported in ≥20% of adult patients treated with ULTOMIRIS were upper respiratory tract infection, diarrhea, nausea, vomiting, headache, hypertension, and arthralgia.[1]

Clinically relevant adverse reactions in <10% of patients included viral tonsillitis.[1]

Serious adverse reactions were reported in 42 (57%) adult and pediatric patients with atypical-HUS receiving ULTOMIRIS. The most frequent serious adverse reactions reported in more than 2 patients (2.7%) treated with ULTOMIRIS were hypertension, pneumonia, and abdominal pain.[1]

Four patients died during the adult atypical-HUS study. Patient deaths were determined by study investigators as unrelated to study drug; the cause of death was sepsis in two patients and intracranial hemorrhage in one patient. The fourth patient, who was excluded from the trial after a diagnosis of STEC-HUS, died due to pretreatment cerebral arterial thrombosis.[1]

*Grouped term includes nasopharyngitis, pharyngitis, upper respiratory tract infection, rhinitis, viral upper respiratory tract infection, rhinovirus infection, viral pharyngitis, rhinorrhea, and oropharyngeal pain.
**Grouped term includes gastroenteritis, gastrointestinal infection, enterocolitis infection, infectious colitis, and enterocolitis.
***Graded per CTCAE v5.0.
CTCAE=Common Terminology Criteria for Adverse Events.

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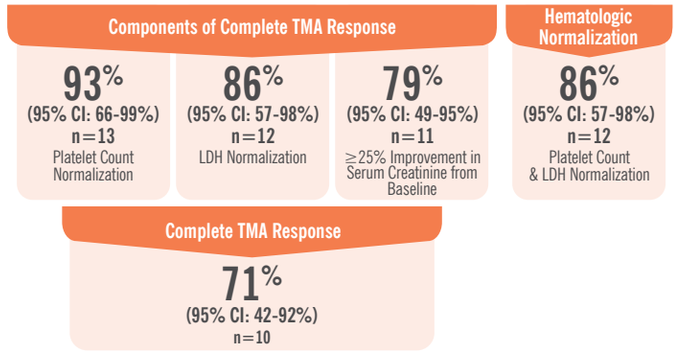
IMMEDIATE C5 inhibition was observed on day 1 in pediatric patients[5]

100% (14/14) of pediatric patients in a 26-week study demonstrated complete C5 inhibition after the first infusion of ULTOMIRIS[5,a]

COMPLETE TMA response was achieved in nearly 3 of 4 pediatric patients taking ULTOMIRIS in a 26-week study[1]



- **100% (10/10)** of complete TMA responses were maintained through all available follow-up in pediatric patients[1,b]
- **99.6%** of all free C5 serum samples in pediatric patients showed complete inhibition of C5 throughout the 6-month study period with ULTOMIRIS[a]

SUSTAINED C5 inhibition and an opportunity to discontinue dialysis in pediatric patients[1]

4 or 8 weeks of sustained C5 inhibition in pediatric patients[1]

At 26 weeks:

An opportunity for your pediatric patients to discontinue dialysis

- 4 of the 5 patients (80%) who required dialysis at study entry discontinued dialysis after the first month in study and for the duration of ULTOMIRIS treatment[1,b]
- No patient started dialysis during the study[1,b]

Potential for recovery of kidney function in your pediatric patients

- Mean eGFR was 108.0 mL/min/1.73 m^2 at end of study, a 79.6 mL/min/1.73 m^2 (280%) mean increase from baseline[1,b]

Pediatric Study Design

- 26-week, ongoing, multicenter, open-label, single-arm study of 14 eculizumab-naïve patients with documented diagnosis of atypical-HUS[1]
- Inclusion: platelet count ≤150 x 10^9/L, evidence of hemolysis such as an elevation in serum LDH, and serum creatinine ≥97.5% percentile at screening or required dialysis[1]
- Exclusion: patients with TMA due to ADAMTS13 deficiency, STEC-HUS, and genetic defect in cobalamin C metabolism[1]
- Primary end point: complete TMA response,[c] which comprised: platelet count normalization (≥150 × 10^9/L), serum LDH normalization (less than upper limit of normal), and ≥25% improvement in serum creatinine from baseline[1,5]
- Select secondary end points: time to complete TMA response and complete TMA response status over time, dialysis requirement and CKD stage as evaluated by eGFR, hemoglobin response, and change from baseline in quality of life[5]

Please see the Prescribing Information for demographics and baseline characteristics of patients in Study 312.

[a]As measured by free C5 serum concentration of <0.5 mcg/mL.[1]
[b]Secondary end point.[5]
[c]Complete TMA response was defined as normalization of hematological parameters (platelet count and LDH) and ≥25% improvement in serum creatinine from baseline during the 26-week initial evaluation period. Patients had to meet all criteria at 2 separate assessments obtained at least 4 weeks (28 days) apart and any measurement in between.[1]

Adverse Reactions Reported in ≥10% of ULTOMIRIS-Treated Pediatric Patients With Atypical-HUS[1]

BODY SYSTEM ADVERSE REACTION	PEDIATRIC PATIENTS (N=16) All Grades** (n=16) n (%)	PEDIATRIC PATIENTS (N=16) ≥ Grade 3 (n=6) n (%)
Blood and lymphatic system disorders		
Anemia	2 (13)	1 (6)
Lymphadenopathy	2 (13)	0 (0)
Gastrointestinal disorders		
Diarrhea	6 (38)	0 (0)
Constipation	4 (25)	0 (0)
Vomiting	4 (25)	1 (6)
Abdominal pain	3 (19)	0 (0)
Nausea	2 (13)	0 (0)
General disorders and administration site conditions		
Pyrexia	8 (50)	0 (0)
Infections and infestations		
Upper respiratory tract infection*	7 (44)	1 (6)
Gastroenteritis viral	2 (13)	2 (13)
Pneumonia	2 (13)	1 (6)
Tonsillitis	2 (13)	0 (0)
Injury, poisoning, and procedural complications		
Contusion	3 (19)	0 (0)
Investigations		
Vitamin D decreased	3 (19)	0 (0)
Metabolism and nutrition disorders		
Decreased appetite	2 (13)	0 (0)
Iron deficiency	2 (13)	0 (0)
Musculoskeletal and connective tissue disorders		
Myalgia	3 (19)	0 (0)
Pain in extremity	2 (13)	0 (0)
Nervous system disorders		
Headache	5 (31)	0 (0)
Respiratory, thoracic, and mediastinal disorders		
Cough	3 (19)	0 (0)
Dyspnea	2 (13)	0 (0)
Skin and subcutaneous tissue disorders		
Rash	3 (19)	0 (0)
Vascular disorders		
Hypertension	4 (25)	1 (6)
Hypotension	2 (13)	0 (0)

The most frequent adverse reactions reported in ≥20% of pediatric patients treated with ULTOMIRIS were upper respiratory tract infection, diarrhea, constipation, vomiting, headache, hypertension, and pyrexia.[1]

Clinically relevant adverse reactions in <10% of patients included viral infection.[1]

Serious adverse reactions were reported in 42 (57%) adult and pediatric patients with atypical-HUS receiving ULTOMIRIS. The most frequent serious adverse reactions reported in more than 2 patients (2.7%) treated with ULTOMIRIS were hypertension, pneumonia, and abdominal pain.[1]

*Grouped term includes nasopharyngitis, pharyngitis, upper respiratory tract infection, rhinitis, viral upper respiratory tract infection, rhinovirus infection, viral pharyngitis, rhinorrhea, and oropharyngeal pain.
**Graded per CTCAE v5.0.

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Alexion: A Long-Standing History of Commitment to Supporting Patients with Rare Diseases

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2
INDICATIONS

4
PHASE 3 CLINICAL TRIALS

>500
PATIENTS STUDIED

With 20 years of complement research experience and over a decade of providing complement inhibition in the clinical setting, Alexion is committed to bringing therapies to patients with rare diseases.

ONESOURCE®
Personalized Patient Support from Alexion
1.888.765.4747 • OneSource@Alexion.com

Education | Community Connections | Health Insurance Navigation | Ongoing Support

OneSource™ is a complimentary, personalized patient support program offered by Alexion

References: 1. ULTOMIRIS [prescribing information]. Boston, MA: Alexion Pharmaceuticals, Inc.; 2020. **2**. Soliris [prescribing information]. Boston, MA: Alexion Pharmaceuticals, Inc.; 2019. **3.** Sheridan D, et al. *PLoS One.* 2018;13(4):e0195909. **4.** Data on file [ALXN1210-aHUS-311CSR]. **5.** Data on file [ALXN1210-aHUS-312CSR].

SELECT IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS MENINGOCOCCAL INFECTIONS

Life-threatening meningococcal infections/sepsis have occurred in patients treated with ULTOMIRIS. Meningococcal infection 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 meningococcal vaccines at least 2 weeks prior to administering the first dose of ULTOMIRIS, unless the risks of delaying ULTOMIRIS therapy outweigh the risk of developing a meningococcal infection. See *Warnings and Precautions* for additional guidance on the management of the risk of meningococcal infection.**
- **Vaccination reduces, but does not eliminate, the risk of meningococcal infections. Monitor patients for early signs of 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 REMS.

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ALEXION®