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

POCKET DOSING GUIDE

- **ULTOMIRIS is the first and only long-acting complement inhibitor for pediatric and adult patients[1]**
- **ULTOMIRIS 100 mg/mL is an advanced formulation of ULTOMIRIS that provides a quicker infusion time, allowing you to infuse your patients with PNH or atypical-HUS with up to 8 weeks of freedom[1,a]**

[a]Starting 2 weeks after the intravenous loading dose, maintenance doses are infused intravenously every 8 weeks for adult patients and every 4 or 8 weeks for pediatric patients (depending on body weight).

INDICATIONS

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

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

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

Subcutaneous Use in Adult Patients with PNH or 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 additional Important Safety Information on pages 8-10 and accompanying full Prescribing Information (bit.ly/UltomirisPI) for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening meningococcal infections/sepsis.

Recommended dosing regimen for patients with PNH or atypical-HUS

ULTOMIRIS is administered once every 8 weeks in adult patients or once every 4 or 8 weeks in pediatric patients (based on body weight).

ULTOMIRIS 100 mg/mL

The recommended dosing regimen consists of a loading dose followed by maintenance doses[1]

Adult patients with PNH or atypical-HUS	Pediatric patients with PNH or atypical-HUS (≥1 month of age and weighing ≥5 kg)
Starting 2 weeks after the initial loading dose, maintenance doses are administered once every 8 weeks	Starting 2 weeks after the initial loading dose, maintenance doses are administered once every 4 or 8 weeks (depending on body weight)

Dosing considerations for patients with PNH and patients with atypical-HUS

- The dosing schedule is allowed to occasionally vary within 7 days of the scheduled infusion day (except for the first maintenance dose of ULTOMIRIS), but the subsequent doses should be administered according to the original schedule[1]

ULTOMIRIS is administered based on weight

Body weight range (kg)	Loading dose (mg)	Maintenance dose (mg) and dosing interval
5 to <10	600	300 Every 4 weeks
10 to <20	600	600 Every 4 weeks
20 to <30	900	2,100 Every 8 weeks
30 to <40	1,200	2,700 Every 8 weeks
40 to <60	2,400	3,000 Every 8 weeks
60 to <100	2,700	3,300 Every 8 weeks
100 or greater	3,000	3,600 Every 8 weeks

Considerations for adult and pediatric patients with PNH or atypical-HUS transitioning from eculizumab to ULTOMIRIS[1]

- Loading dose of ULTOMIRIS should be administered at the time of the next scheduled eculizumab dose[1]
- ULTOMIRIS maintenance doses are administered once every 4 or 8 weeks (based on body weight), starting 2 weeks after the loading dose[1]

Administration of ULTOMIRIS for patients with PNH or atypical-HUS

ULTOMIRIS 100 mg/mL is an advanced formulation of ULTOMIRIS to provide a quicker infusion time for your patients every 4 or 8 weeks, based on body weight.

ULTOMIRIS weight-based dosing: 100 mg/mL formulation[1]

	Body weight range[a] (kg)	ULTOMIRIS volume		Volume of 0.9% NaCl[b]		Total volume (dose)	Minimum infusion time (hr)	Maximum infusion rate (mL/hr)
Loading dose administration	5 to <10	6 mL	+	6 mL	=	12 mL (600 mg)	1.4	9
	10 to <20	6 mL	+	6 mL	=	12 mL (600 mg)	0.8	15
	20 to <30	9 mL	+	9 mL	=	18 mL (900 mg)	0.6	30
	30 to <40	12 mL	+	12 mL	=	24 mL (1,200 mg)	0.5	48
	40 to <60	24 mL	+	24 mL	=	48 mL (2,400 mg)	0.8	60
	60 to <100	27 mL	+	27 mL	=	54 mL (2,700 mg)	0.6	90
	100 or greater	30 mL	+	30 mL	=	60 mL (3,000 mg)	0.4	150
Maintenance dose administration	5 to <10	3 mL	+	3 mL	=	6 mL (300 mg)	0.8	8
	10 to <20	6 mL	+	6 mL	=	12 mL (600 mg)	0.8	15
	20 to <30	21 mL	+	21 mL	=	42 mL (2,100 mg)	1.3	33
	30 to <40	27 mL	+	27 mL	=	54 mL (2,700 mg)	1.1	50
	40 to <60	30 mL	+	30 mL	=	60 mL (3,000 mg)	0.9	67
	60 to <100	33 mL	+	33 mL	=	66 mL (3,300 mg)	0.7	95
	100 or greater	36 mL	+	36 mL	=	72 mL (3,600 mg)	0.5	144

[a]Body weight at time of treatment.[1]

[b]Dilute ULTOMIRIS only using 0.9% Sodium Chloride Injection, USP.[1]

If an adverse reaction occurs during the intravenous administration of ULTOMIRIS, the infusion may be slowed or stopped at the discretion of the physician.

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

Ordering vials for patients with PNH or atypical-HUS

The ULTOMIRIS 100 mg/mL formulation comes in 2 single-dose vials, 1,100 mg/11 mL (aqua cap) and 300 mg/3 mL (lavender cap), and is a translucent, clear to yellowish color. With ULTOMIRIS 100 mg/mL, there is an optimal vial mix (3 mL and 11 mL) for each patient weight cohort, ensuring there is no product wastage.

Number of vials needed for ULTOMIRIS weight-based dosing: 100 mg/mL formulation[1]

	Body weight range (kg)	ULTOMIRIS volume	ULTOMIRIS vial combinations	
			1,100 mg/11 mL	300 mg/3 mL
Loading dose administration	5 to <10	6 mL		2
	10 to <20	6 mL		2
	20 to <30	9 mL		3
	30 to <40	12 mL		4
	40 to <60	24 mL		8
	60 to <100	27 mL		9
	100 or greater	30 mL		10
Maintenance dose administration	5 to <10	3 mL		1
	10 to <20	6 mL		2
	20 to <30	21 mL		7
	30 to <40	27 mL		9
	40 to <60	30 mL		10
	60 to <100	33 mL	3	
	100 or greater	36 mL	3	1

100 mg/mL (3 mL vial):
J code, J1303;
National Drug Code,
NDC 25682-025-01

100 mg/mL (11 mL vial):
J code, J1303;
National Drug Code,
NDC 25682-028-01

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Supplemental dose of ULTOMIRIS

Plasma exchange (PE), plasmapheresis (PP), and intravenous immunoglobulin (IVIg) treatment have been shown to reduce ULTOMIRIS serum levels. A supplemental dose of ULTOMIRIS is required in the setting of PE, PP, or IVIg.

Supplemental dose of ULTOMIRIS after PE, PP, or IVIg[1]

Body weight range (kg)	Most recent ULTOMIRIS dose (mg)	Supplemental dose (mg) following each PE or PP intervention	Supplemental dose (mg) following completion of an IVIg cycle
40 to <60	2,400	1,200	600
	3,000	1,500	
60 to <100	2,700	1,500	600
	3,300	1,800	
100 or greater	3,000	1,500	600
	3,600	1,800	
Timing of ULTOMIRIS supplemental dose		Within 4 hours following each PE or PP intervention	Within 4 hours following completion of an IVIg cycle

ULTOMIRIS supplemental dose reference table: 100 mg/mL formulation[1]

Body weight range[a] (kg)	Supplemental dose (mg)	ULTOMIRIS volume		Volume of 0.9% NaCl[b]		Total volume	Minimum infusion time (hr)	Maximum infusion rate (mL/hr)
40 to <60	600	6 mL	+	6 mL	=	12 mL	0.25	48
	1,200	12 mL	+	12 mL	=	24 mL	0.42	57
	1,500	15 mL	+	15 mL	=	30 mL	0.50	60
60 to <100	600	6 mL	+	6 mL	=	12 mL	0.20	60
	1,500	15 mL	+	15 mL	=	30 mL	0.36	83
	1,800	18 mL	+	18 mL	=	36 mL	0.42	86
100 or greater	600	6 mL	+	6 mL	=	12 mL	0.17	71
	1,500	15 mL	+	15 mL	=	30 mL	0.25	120
	1,800	18 mL	+	18 mL	=	36 mL	0.28	129

[a]Body weight at time of treatment.

[b]Dilute ULTOMIRIS only using 0.9% Sodium Chloride Injection, USP.

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Preparing and administering ULTOMIRIS[1]

1 Weigh patient

2 Determine **how many ULTOMIRIS vials are needed based on patient weight and prescribed dose** (see pages 2-5 for reference)

- Vials should be stored under refrigeration at 2°C-8°C (36°F-46°F) in the original carton to protect from light. Do not freeze. Do not shake
- Each vial of ULTOMIRIS is intended for single dose only

3 Visually inspect each ULTOMIRIS vial to be sure there is no particulate matter or precipitate (if either, do not use)

4 Using aseptic technique, **withdraw the volume of ULTOMIRIS (corresponding to the prescribed dose) from the appropriate number of vials and add to an equal volume (1:1) of 0.9% Sodium Chloride Injection, USP,** in an infusion bag (see pages 2-5 for reference)

- ULTOMIRIS is supplied in two single-dose vials (1,100 mg/11 mL and 300 mg/3 mL) to enable an optimal vial mix for each weight cohort, ensuring there is no product wastage
- ULTOMIRIS requires dilution to a final concentration of 50 mg/mL for the 3 mL and 11 mL vials

5 **Gently mix** the solution by swirling (do not shake or introduce air bubbles) and protect from light

6 Prior to administration, allow the admixture to adjust to room temperature (18°C-25°C, 64°F-77°F). Do not heat the admixture in a microwave or with any heat source other than ambient air temperature

7 Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit

8 Administer the solution immediately to the patient through a **0.2 or 0.22 micron filter**

- If the solution is not administered immediately, the solution can be stored under refrigeration at 2°C-8°C (36°F-46°F) for ≤24 hours, taking into account the expected infusion time. Do not freeze the solution
- When administering stored (refrigerated) solution, be sure to bring to room temperature naturally before administering, and be sure to administer within 4 hours

9 The **length of infusion time will vary** based on the dose as determined by the patient's weight, but the rate of infusion should not exceed the maximum for each dose (see page 4 for reference)

10 **Monitor patient for at least 1 hour following infusion** to ensure no signs or symptoms of an infusion-related reaction occur

- If an adverse reaction occurs during the administration of ULTOMIRIS, the infusion may be slowed or stopped at the discretion of the physician. Interrupt ULTOMIRIS infusion and institute appropriate supportive measures if signs of cardiovascular instability or respiratory compromise occur
- Some signs of infusion-related reaction include lower back pain, drop in blood pressure, elevation in blood pressure, limb discomfort, drug hypersensitivity (allergic reaction), dysgeusia (bad taste), and drowsiness

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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.

In clinical studies, 59 adult patients with PNH were treated with ULTOMIRIS less than 2 weeks after meningococcal vaccination. All of these 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 ULTOMIRIS have not been established. In clinical studies with ULTOMIRIS, <1% of patients developed serious meningococcal infections/sepsis while receiving treatment with ULTOMIRIS. All were adult patients with PNH who had been vaccinated. These patients recovered while continuing treatment with ULTOMIRIS. 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

Treatment Discontinuation for PNH

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

Treatment Discontinuation for aHUS

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

TMA complications post-discontinuation can be identified if any of the following is observed: Clinical symptoms of TMA include changes in mental status, seizures, angina, dyspnea, thrombosis or increasing blood pressure. In addition, at least two of the following laboratory signs observed concurrently and results should be confirmed by a second measurement 28 days apart with no interruption: a decrease in platelet count of 25% or more as compared to either baseline or to peak platelet count during ULTOMIRIS treatment; an increase in serum creatinine of 25% or more as compared to baseline or to nadir during ULTOMIRIS treatment; or, an increase in serum LDH of 25% or more as compared to baseline or to nadir during ULTOMIRIS treatment. If TMA complications occur after discontinuation, consider reinitiation of ULTOMIRIS treatment or appropriate organ-specific supportive measures.

Thromboembolic Event Management

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

Infusion-Related Reactions

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
Adverse Reactions for PNH
Adverse reactions reported in 5% or more of patients treated with ULTOMIRIS vs. Eculizumab was Upper respiratory tract infection (39% vs. 39%), Headache (32% vs. 26%), Diarrhea (9% vs. 5%), Nausea (9% vs. 9%), Pyrexia (7% vs. 8%), Pain in extremity (6% vs. 5%), Abdominal pain (6% vs. 7%), Dizziness (5% vs. 6%), Arthralgia (5% vs. 5%). Serious adverse reactions were reported in 15 (6.8%) patients receiving ULTOMIRIS. The serious adverse reactions in patients treated with ULTOMIRIS included hyperthermia and pyrexia. No serious adverse reaction was reported in more than 1 patient treated with ULTOMIRIS. One fatal case of sepsis was identified in a patient treated with ULTOMIRIS. In clinical studies, clinically relevant adverse reactions in 1% of adult patients include infusion-related reactions.

Adverse reactions reported in 10% or more of pediatric patients treated with ULTOMIRIS who were treatment-naïve vs. Eculizumab-experienced was Anemia (20% vs. 25%), Abdominal pain (0% vs. 38%), Constipation (0% vs. 25%), Pyrexia (20% vs. 13%), Upper respiratory tract infection (20% vs. 75%), Pain in extremity (0% vs. 25%), Headache (20% vs. 25%).

Adverse Reactions for aHUS
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.

ONESOURCE®
Personalized Patient Support from Alexion

$0 in out-of-pocket costs for eligible patients[a,b]

Alexion Patient Liaisons and Patient Navigators, with advanced PNH or atypical-HUS disease education experience and health insurance information, will be assigned to each patient to provide complimentary education and support.

Alexion Patient Liaisons and Patient Navigators assist with:

Education

- Providing your patients with educational resources and materials related to PNH or atypical-HUS
- Helping to answer your patients' questions about the disease or treatment logistics

Continuity of care

- Personalized support for your patients in maintaining therapy during their major life events, such as a change in job, insurance status, provider, or relocation

Health insurance information

- Helping your patients understand ULTOMIRIS health insurance coverage
- Exploring alternative funding options and financial resources

Community connections

- Providing information to patients regarding in-person and online meetings and events
- Connecting patients with other people living with PNH or atypical-HUS

Copay assistance

- The Alexion OneSource CoPay Program provides financial assistance by covering eligible patients' out-of-pocket medication and infusion costs associated with ULTOMIRIS up to $15,000 US dollars per calendar year
- Valid only for patients with commercial insurance who have a valid prescription for a US FDA-approved indication of ULTOMIRIS. Not valid for patients covered by government insurance programs[c] or other federal or state programs (including any state prescription drug assistance programs)
- Additional requirements may apply. Contact Alexion OneSource for more information on patient eligibility

OneSource is here to help **Contact OneSource at 1-888-765-4747**

[a]Based on typical commercial patient out-of-pocket deductible limits.

[b]Additional terms and conditions apply. Please contact OneSource with additional questions.

[c]Includes Medicaid, Medicare (including Medicare Part D), Medicare Advantage Plans, Medigap, Veterans Affairs, Department of Defense, or TRICARE. Patients residing in Massachusetts or Rhode Island are eligible for assistance with medication costs but are not eligible for assistance with infusion costs.

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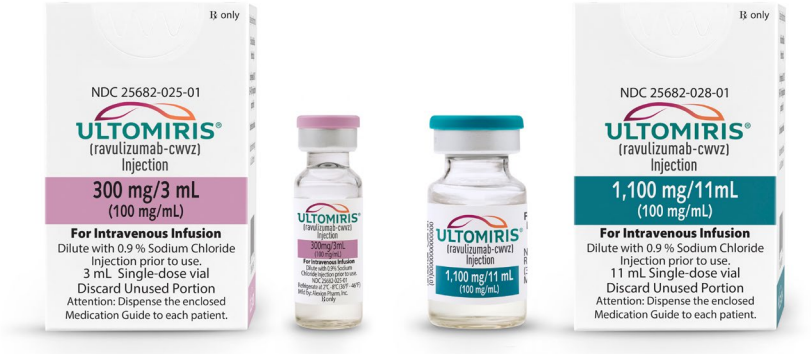
[a]Starting 2 weeks after the intravenous loading dose, maintenance doses are infused intravenously every 8 weeks for adult patients and every 4 or 8 weeks for pediatric patients (depending on body weight).



REFERENCE

1. ULTOMIRIS. Prescribing information. Alexion Pharmaceuticals, Inc.

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ALEXION
AstraZeneca Rare Disease