



# **ULTOMIRIS® (ravulizumab)**

## **Patient/Parent/Legal Guardian Guide**

Paroxysmal Nocturnal Hemoglobinuria (**PNH**)

Atypical Hemolytic Uremic Syndrome (**aHUS**)

Generalized Myasthenia Gravis (**gMG**)

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# 1 INTRODUCTION

ULTOMIRIS® is used to treat adults and children with:

- Paroxysmal Nocturnal Hemoglobinuria (**PNH**)
- Atypical Hemolytic Uremic Syndrome (**aHUS**)

ULTOMIRIS® is also used to treat adults with:

- Generalized Myasthenia Gravis (**gMG**)

This guide is to explain important safety information related to ULTOMIRIS® to patients and parents/legal guardians of infants and children who are prescribed ULTOMIRIS®

ULTOMIRIS® must be prescribed by a doctor.

**You will receive the following materials from your doctor:**

- **Patient Safety Information Card**
  - It is very important to rapidly identify and treat certain types of infection in patients who receive ULTOMIRIS®; therefore, you will be given a card that lists the specific symptoms you must always look for.
  - You must carry this card at all times throughout the duration of your ULTOMIRIS® therapy and for 8 months after the last dose of ULTOMIRIS® and show it to any healthcare professional you see.
- **Patient/Parent/Legal Guardian Guide**

## 2 SAFETY CONSIDERATIONS RELATED TO ULTOMIRIS®

### Risk of Meningococcal infection

- ULTOMIRIS® may reduce your natural resistance to a certain bacteria called *Neisseria meningitidis* that may increase your risk of meningococcal infection. The meningococcal infection can lead to severe swelling of the tissues surrounding the brain and spinal cord (meningitis) and/or a severe infection of the blood (septicaemia, also known as blood poisoning or sepsis).
- These infections require urgent and appropriate care as they may become rapidly fatal or life-threatening or lead to major disabilities<sup>1</sup>.

**Before starting treatment with ULTOMIRIS®:**

- ▶ Your doctor will vaccinate you against meningococcal infection, at least 2 weeks before beginning therapy. If ULTOMIRIS® treatment is initiated less than 2 weeks after receiving meningococcal vaccine, your doctor will make sure that you take antibiotics to reduce the risk of infection until 2 weeks after you have been vaccinated.
- ▶ Vaccination reduces the risk of developing meningococcal infection, but it does not remove the risk completely. Your doctor might consider that you need additional measures to prevent infection.
- ▶ Vaccination or revaccination may further activate complement and, as a result, patients with complement-mediated diseases may experience increased signs and symptoms of their underlying disease.

Ask your doctor if you have any questions about the vaccinations you require before starting ULTOMIRIS®

**During treatment with ULTOMIRIS®:**

- ▶ Be aware of the signs and symptoms of meningococcal infection and notify your doctor immediately if any of these occur.

**The signs and symptoms of meningococcal infection you must look for are:**

- Headache with nausea or vomiting
- Headache and fever
- Headache with a stiff neck or stiff back
- Fever
- Fever and Rash
- Confusion
- Muscle aches with flu-like symptoms
- Eyes sensitive to light

- ▶ Carry the Patient Safety Information Card at all times throughout the duration of your ULTOMIRIS® therapy and for 8 months after the last dose of ULTOMIRIS® and show it to any healthcare professional you see.

If you cannot reach your doctor, go to an emergency department and show them your Patient Safety Information Card.

The signs and symptoms of meningitis can be different in infants and children. These are described under the important safety information for infants and children who are taking ULTOMIRIS®

### **Risk of other infections**

- ULTOMIRIS® treatment may reduce your natural resistance to other similar bacterial infections including gonorrhea which is a sexually transmitted disease.
- Before starting ULTOMIRIS®, tell your doctor if you have any infections.
- If you know that you are at risk of gonorrhea (a sexually transmitted infection), ask your doctor or pharmacist for advice before using this medicine.
- Your doctor will administer a vaccine to your child aged less than 18 years against *Haemophilus influenzae* and pneumococcal infections according to the national vaccination recommendations for each age group.

### **Infusion/Allergic reactions**

- ULTOMIRIS® contains a protein, and proteins may cause infusion or allergic reactions (including anaphylaxis) in some patients.
- If you experience any discomfort during or after ULTOMIRIS® infusion, you should consult your healthcare professional.

### **Pregnancy and breast feeding**

- ULTOMIRIS® is not recommended during pregnancy and in women of childbearing potential not using contraception.
- Ask your doctor for advice before using ULTOMIRIS® if you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby.
- Adequate contraception during treatment and up to 8 months after treatment should be used in women who are able to get pregnant.
- Breastfeeding should be avoided during treatment and up to 8 months after treatment.

### 3 HOW LONG WILL I NEED TO RECEIVE ULTOMIRIS®?

As you have a chronic disease, ULTOMIRIS® is intended to be an ongoing therapy.

**Do not stop treatment without first discussing with your doctor**

#### **If you stop receiving ULTOMIRIS® for PNH**

Interrupting or stopping treatment with ULTOMIRIS® may cause your PNH symptoms to come back more severely.

Your doctor will discuss the possible side effects with you and explain the risks.

Your doctor will monitor you closely for at least 16 weeks.

The risks of stopping ULTOMIRIS® include increased breakage of your red blood cells, which may cause

- An increase in your lactate dehydrogenase (LDH) levels, a laboratory marker of destruction of red blood cells,
- A large drop in the number of red blood cells (anaemia),
- Dark coloured urine,
- Fatigue,
- Abdominal pain,
- Shortness of breath,
- Difficulty swallowing,
- Impotence (erectile dysfunction),
- Confusion or change in how alert you are,
- Chest pain (angina),
- Problems with your kidneys (an increase in your serum creatinine level),
- Blood clotting (thrombosis).

If you have any of the above contact your doctor.

## If you stop receiving ULTOMIRIS® for aHUS

Interrupting or ending treatment with ULTOMIRIS® may cause your aHUS symptoms to come back.

Your doctor will discuss the possible side effects with you and explain the risks.

Your doctor will monitor you closely.

The risks of stopping ULTOMIRIS® include an increase in small blood vessel damage, which may cause:

- A large drop in the number of platelets (thrombocytopenia),
- A large increase in destruction of your red blood cells (anaemia),
- An increase in your lactate dehydrogenase (LDH) levels, a laboratory marker of destruction of red blood cells,
- Problems with your kidneys (decreased urination, an increase in your creatinine level),
- Confusion or change in how alert you are,
- Change in your vision,
- Chest pain (angina),
- Shortness of breath,
- Abdominal pain, diarrhea or
- Blood clotting (thrombosis).

If you have any of the above, contact your doctor.

## If you stop receiving ULTOMIRIS® for gMG

As gMG is a chronic disease, you should monitor for recurrence of its symptoms if your treatment with ULTOMIRIS® is discontinued.

If symptoms of gMG occur after discontinuation, reach out to your doctor for appropriate treatment.

## 4 IMPORTANT SAFETY INFORMATION FOR INFANTS AND CHILDREN WHO ARE RECEIVING ULTOMIRIS®

This section is for parents/ legal guardians of infants and young children who are receiving ULTOMIRIS®. Meningococcal infections are extremely dangerous and may become life-threatening within hours.

### **Common Signs and Symptoms of Meningitis and Severe Blood Infection (Sepsis) in infants and children<sup>2,3</sup>**

- Fever, cold hands and feet
- Fretful, dislike being handled
- Rapid breathing or grunting
- Unusual cry, moaning
- Stiff neck, dislike bright lights
- Refusing food and vomiting
- Drowsy, floppy, unresponsive
- Pale, blotchy skin spots/rash
- Tense, bulging fontanelle (soft spot on the baby's head)
- Convulsions/seizures

In children, additional signs and symptoms to those listed for infants may include:<sup>3</sup>

- Severe muscle pain
- Severe headache
- Confusion
- Irritability

Do not wait until a rash appears<sup>1,2</sup>. If your child is ill and getting worse, get medical help immediately.

**Meningitis symptoms can appear in any order. Some may not appear at all. It is very important to seek medical care immediately if you see any of the above signs and symptoms.**



## Patient Safety Information Card

The Patient Safety Information Card contains important safety information that you or anyone responsible for the care of your child should know throughout the duration of your child's ULTOMIRIS® therapy and for 8 months after the last dose of ULTOMIRIS®.

Fill out the card and give one to anyone responsible for the care of your child (for example a teacher, babysitter/nanny, daycare center staff). Also, be sure to carry a copy with you at all times. Extra copies of this guide and the Patient Safety Information Card may be obtained from your healthcare professional.

**Tell the person responsible for the care of your child that these cards should be shown to any healthcare professional involved in your child's treatment, should your child need medical attention.**

**If your child shows any signs or symptoms of meningitis or severe blood infection (sepsis), contact their healthcare provider immediately.**

If you cannot reach the healthcare professional, seek **immediate** emergency care at an emergency department and show the staff the child's Patient Safety Information Card.

## FURTHER INFORMATION

For more information about ULTOMIRIS®, please ask your doctor or pharmacist.

If you experience any side effects, including side effects not listed in this Guide, consult your doctor or pharmacist.

This document has been approved by Singapore Health Sciences Authority (HSA) on 19-JUN-2024.

## REFERENCES

1. Meningitis explained. Meningitis Now website. Available at: <https://www.meningitisnow.org/meningitis-explained/after-meningitis/> (Accessed: 04 November 2022).
2. Signs and symptoms of meningitis in babies and toddlers. Meningitis Now website. Available at: <https://www.meningitisnow.org/meningitis-explained/signs-and-symptoms/signs-and-symptoms-babies-and-toddlers/> (Accessed: 04 November 2022).
3. Meningitis symptoms in children. Meningitis Now website. Available at: <https://www.meningitisnow.org/meningitis-explained/signs-and-symptoms/signs-and-symptoms-children/> (Accessed: 04 November 2022)

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