
ULTOMIRIS[®] (ravulizumab)

Guide for Patients/Parents/Caregivers

This guide is intended to explain important safety information of ULTOMIRIS[®] to patients and parents/caregivers of infants and children who are prescribed ULTOMIRIS[®] and describes:

- What is ULTOMIRIS[®]?
- Important safety information related to ULTOMIRIS[®]
- Important safety information for parents/caregivers of infants and children who are receiving ULTOMIRIS[®]
- Patient Card
- Further Information

WHAT IS ULTOMIRIS®?

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**)
- Neuromyelitis Optica Spectrum Disorder (**NMOSD**)

ULTOMIRIS® must be prescribed by a doctor.

IMPORTANT INFORMATION 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.

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, you may experience increased signs and symptoms of your 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.
- **If you cannot reach your doctor, go to an emergency department and show them your Patient Card (see Page 6).** Meningococcal infections are extremely dangerous and may become life-threatening within hours.

Early symptoms of a meningococcal infection that you must look out for are:

- Fever
- Headache
- Vomiting
- Diarrhea
- Muscle pain
- Stomach cramps
- Fever with cold hands and feet

Other signs and symptoms of meningococcal infection can include:

- Headache with nausea or vomiting
- Headache and fever
- Headache with a stiff neck or stiff back
- Fever and rash
- Confusion
- Muscle aches with flu-like symptoms
- Eyes sensitive to light
- **Please carry the Patient Card with you 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.**
- The signs and symptoms of meningitis can be different in infants and children. These are described under the important safety information for parents/caregivers of infants and children who are receiving 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. If you know that you are at risk of gonorrhea, ask your doctor for advice before using this medicine.
- Before starting ULTOMIRIS®, tell your doctor if you have any infections.
- A doctor will administer a vaccine (if not yet done) to a child aged less than 18 years against *Haemophilus influenzae* and pneumococcal infections according to the national vaccination recommendations for each age group.

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 breastfeeding, 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.

If you stop receiving ULTOMIRIS® for PNH

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

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 (anemia),
- 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 (anemia),
- 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 and NMOSD

As gMG and NMOSD are chronic diseases, you should monitor for recurrence of its symptoms if your treatment with ULTOMIRIS® is discontinued.

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

IMPORTANT SAFETY INFORMATION FOR PARENTS/CAREGIVERS OF INFANTS AND CHILDREN WHO ARE RECEIVING ULTOMIRIS®

Common Signs and Symptoms of Meningitis and Severe Blood Infection (Sepsis) in infants and children

- 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:

- Severe muscle pain
- Severe headache
- Confusion
- Irritability

Do not wait until a rash appears. 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 CARD

You will receive a Patient Card from your doctor:

- It is very important to rapidly identify and be treated for 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.
- You may also 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). Extra copies of the 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.

FURTHER INFORMATION

If you have any questions about ULTOMIRIS® or experience any side effects from your treatment, please consult your doctor or pharmacist.

This document has been approved by HSA as of 19-05-2025.

