

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
- Patient Card
- Important safety information for infants and children who are receiving ULTOMIRIS
- Contact 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 reduces your natural resistance to a certain bacteria called *Neisseria meningitidis* that increases 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.
- 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.**

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

You will be provided with a Patient Card (see below). Please carry this 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 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.
- 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.
- Administer ULTOMIRIS therapy with caution to patients with active systemic infections.

If you stop using 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),
 - Problems with your kidneys (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, diarrhoea, or
 - Blood clotting (thrombosis).
- If you have any of the above, contact your doctor.

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.

Important Safety Information for Infants and Children Who Are Receiving ULTOMIRIS

Meningococcal infections are extremely dangerous and may become life-threatening within hours. Early symptoms of meningitis can include:

- Fever
- Headache
- Vomiting
- Diarrhoea
- Muscle pain

- Stomach cramps
- Fever with cold hands and feet

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 for a rash. 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.

Paediatric Safety Information Card

The Paediatric 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 centre staff). Also, be sure to carry a set with you at all times. Extra copies of this guide and Paediatric Safety Information Card are available for free by emailing the Registration Holder's Patient Safety Unit at: drugsafety@neopharmgroup.com, or calling: 1-800-250-255.

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

If the 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 Paediatric Safety Information Card.

CONTACT INFORMATION

If you experience any side effects from your treatment with ULTOMIRIS, please report these to the Israeli Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" that appears on the homepage of the Israeli Ministry of Health's website (www.health.gov.il) which links to a portal, or by the following link: <https://sideeffects.health.gov.il/> and by emailing the Registration Holder's Patient Safety Unit at: drugsafety@neopharmgroup.com Tel: 1-800-250-255.

REFERENCES

ULTOMIRIS (ravulizumab) Prescribing Information as approved by the Israeli MOH.

Front of the card

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Paediatric Safety Information Card

**IMPORTANT INFORMATION FOR
SUPERVISING INDIVIDUALS** 

This child is currently being treated with ULTOMIRIS and has reduced natural resistance to infections, especially meningococcal infections, which include meningitis and severe blood infection or blood poisoning (also known as sepsis). If you notice that the child has any of the signs or symptoms listed on this card, which could indicate a serious infection, call the child's doctor immediately.

FOLD →

Patient name: _____

Parent/Guardian contact information: _____

Physician name: _____

If you cannot reach the child's doctor, take the child to the emergency department immediately and show the staff this card. Even if the child has stopped using ULTOMIRIS, keep this card with you for 8 months after the child's last ULTOMIRIS dose.

Physician contact information: _____

Back of the card



Meningitis can become life-threatening within hours. If **ANY** signs or symptoms should appear, seek medical attention immediately.

Meningitis and severe blood infection (sepsis) symptoms for infants and children:

COMMON SIGNS AND SYMPTOMS:

- Fever, cold hands and feet
- Stiff neck, dislikes bright lights
- Rapid breathing or grunting
- Pale, blotchy skin; spots/rash
- Refusing food and vomiting
- Fretful, dislikes being handled
- Drowsy, floppy, unresponsive
- Unusual cry, moaning
- Tense, bulging fontanelle (soft spot)
- Convulsions/seizures
- Severe muscle pain
- Severe headache
- Confusion
- Irritability

IMPORTANT SAFETY INFORMATION FOR HEALTHCARE PROFESSIONALS

This patient was prescribed ULTOMIRIS therapy. ULTOMIRIS is an antibody that inhibits terminal complement activation. Due to its mechanism of action, the use of SOLIRIS increases the patient's susceptibility to meningococcal infection (*Neisseria meningitidis*).

Before beginning treatment, this patient should have received a meningococcal vaccine, but they may still be susceptible to meningococcal infections or other general infections. You should carefully monitor the emergence of early signs of meningococcal infection, evaluate immediately if infection is suspected, and treat with antibiotics if necessary.

For more information about ULTOMIRIS, please refer to the Israeli approved Prescribing Information. In case of safety concerns, please report to the Israeli Ministry of Health by the following link: <https://sideeffects.health.gov.il/> and by emailing the Registration Holder's Patient Safety Unit at: drugsafety@neopharmgroup.com Tel: 1-800-250-255.

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