Patient Safety Information Card

ULTOMIRIS® (ravulizumab)

Patients receiving ULTOMIRIS® should carry this card with them at all times.
Show this card to any healthcare professional involved in your or the child's treatment.

Important Safety Information for Patients

ULTOMIRIS® can lower the ability of your immune system to fight infections, especially meningococcal infection, which requires immediate medical attention. If you experience any of the signs and symptoms listed on this card, you should immediately call your doctor or seek emergency medical care, preferably in a major emergency medical care center.

For Parents/Guardians of Pediatric Patients

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

For Supervising Individuals of Pediatric Patients

This child is currently being treated with ULTOMIRIS® and may have 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 or seek immediate emergency care at an emergency department and show this card to them.

Common signs and symptoms of meningitis and severe blood infection

In adults:

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

In infants and children:

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

Even if you or the child has stopped using ULTOMIRIS® keep this card with you for 8 months after the last ULTOMIRIS® dose. The risk of meningococcal infection may continue for several weeks after the last dose of ULTOMIRIS®.

Get emergency medical care right away if you or the child have any of these signs or symptoms and show this card

- Meningitis can become life-threatening within hours.
- If ANY sign or symptom should appear, seek medical attention immediately.

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 ULTOMIRIS® 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.

Some patients have experienced infusion reactions following administration of ULTOMIRIS®. Common general disorders or administration site conditions include chest discomfort, chills, fatigue, asthenia, infusion-related reaction, oedema, and pyrexia. For more information about ULTOMIRIS®, please refer to the package insert. In case of safety concerns, please contact PatientSafety.SG@astrazeneca.com

Patient name: _____

Hospital (where ULTOMIRIS® was initiated): _____

Parent/Guardian information (if applicable): _____

Physician name: _____

Physician contact information: _____

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

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