ULTOMIRIS® ▼ (ravulizumab)

Parent/Guardian Guide

Important Information about the risk of serious infections including meningitis and sepsis in children and infants

▼ This medicine is subject to additional monitoring.
This will allow quick identification of new safety information.
You can help by reporting any side effects you may get.

ALEXION®
AstraZeneca Rare Disease

Ultomiris_Parent/ Guardian Guide_V4 Revised in December 2021

RAVULIZUMAB – HELPING YOU MANAGE PNH / aHUS

Ravulizumab is a medicine to treat a rare blood disease called PNH and a serious illness called aHUS. These illnesses are not caused by bacteria or a virus, so are not contagious or spreadable to others. Ravulizumab targets a part of the immune system, and thus can make the child more susceptible to certain serious infections.

Please read this brochure and make sure you understand it. If you have any questions speak to your doctor or pharmacist.

FREQUENTLY ASKED QUESTIONS

WHAT STEPS SHOULD BE TAKEN BEFORE MY CHILD STARTS RAVULIZUMAB THERAPY?

Prior to your child commencing treatment with ravulizumab, your doctor will discuss with you the importance of:

- Vaccine administration against meningitis and, in some cases, specific antibiotic(s) to reduce the risk of infection with a type of bacteria called *Neisseria meningitidis.*
- Other vaccination requirements, such as *Haemophilus influenza* and pneumococcal vaccines.
- Understanding the symptoms associated with infections that are listed in the educational materials you have received and what to do if your child experiences these symptoms.

WHAT ARE THE SAFETY CONSIDERATIONS RELATED TO RAVULIZUMAB?

IMPORTANT SAFETY INFORMATION

As ravulizumab blocks a part of the body's immune system, your child's natural resistance to infections may be reduced, especially against certain organisms that cause meningococcal infections, including meningitis (severe infection of the linings of the brain) and septicaemia (also known as blood poisoning or sepsis).

Meningococcal infections are severe and require urgent and appropriate care, as they may become rapidly fatal or life-threatening or lead to major disabilities.

It is important to understand the precautions to take to reduce the risk of these infections and what to do if you suspect your child may have an infection (see below).

If your child experiences any sign or symptoms of infection, seek **IMMEDIATE** medical attention.

VACCINATION AND/OR ANTIBIOTIC MEDICINE

To reduce the risk of severe infections your child will need to take certain precautions.

Your healthcare professional may give your child a vaccination and/or antibiotic medicine to decrease the chance of your child getting a meningococcal infection.

In addition, your child will be closely monitored for meningococcal and other infections during the course of the therapy.

If your child has not received a meningococcal vaccine or antibiotics, speak to your doctor immediately and before treatment with ravulizumab begins.

YOUR CHILD MUST BE VACCINATED against meningococcal infection at least 2 weeks before receiving the first ravulizumab infusion or must receive antibiotics until 2 weeks after vaccination. However, vaccination and antibiotics cannot fully protect against the possibility that your child may become infected with meningitis.

If your child initiates ravulizumab treatment less than 2 weeks after receiving a meningococcal vaccine, your child must receive antibiotic(s) until 2 weeks after vaccination to reduce the risk of infection with *Neisseria meningitidis*.

If no vaccine is available for your young child or if the vaccine is contraindicated, your child will be given an antibiotic throughout the treatment period or until 2 weeks after the vaccine can be given.

Vaccination reduces the risk of developing meningococcal infection, but it does not eliminate the risk completely.

Children and adolescents less than 18 years of age will need to be vaccinated against *Haemophilus influenza* and pneumococcal infections at least 2 weeks prior to initiation of ravulizumab therapy and will need to follow the national vaccination recommendations for their age group.

WHAT ARE THE SIGNS AND SYMPTOMS OF MENINGITIS AND/OR SEPSIS THAT SHOULD ALERT ME TO IMMEDIATELY INFORM MY CHILD'S DOCTOR?

If you are a parent/legal guardian of an infant or child who is receiving ravulizumab therapy, it is important to be aware that signs and symptoms of meningitis and/or sepsis can vary according to your child's age.

You should IMMEDIATELY inform your doctor and seek URGENT medical attention, if your child experiences ANY of the following meningococcal infection symptoms[1]:

- **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**

Symptoms of meningitis can appear in any order.
Some may not appear at all. In the early stages, there may not be a rash, or the rash may fade on pressure

In infants additional signs and symptoms to those listed above may include:

- rapid breathing
- cold hands and feet
- refusing food and/or vomiting
- unusual crying or moaning
- baby is drowsy, floppy or unresponsive
- bulging of baby's soft spot

In children additional signs and symptoms to those listed above may include:

- stiff neck
- being drowsy or difficult to wake
- irritability
- fits (seizures)

PATIENT ALERT CARD

The Patient Alert 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 ravulizumab therapy and beyond. Because ravulizumab may reduce your child's natural resistance to infections, it is important to recognise the signs and symptoms of infections, including those of meningitis and sepsis. This card includes a list of the signs and symptoms of these infections, so anyone supervising your child can recognise meningitis and sepsis, and seek **IMMEDIATE** medical attention.

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

Your healthcare professional will fill out the card and give it to you. The parent/guardian must carry the card at all times for the duration of the child's treatment and for a period of 8 months after medicine is stopped. Your child's risk of meningococcal infections may continue for several months after their final dose of ravulizumab.

PATIENT ALERT CARD

ALEXION

Important Safety Information for Patients taking Ultomiris® ▽ (ravulizumab)

▽This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

Ravulizumab 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 following symptoms, you should immediately call your doctor or seek emergency medical care, preferably in a major emergency medical care centre:

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

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

Keep this card with you at all times during treatment and for 8 months after your last ravulizumab dose. Your risk of meningococcal infection may continue for several months after your last dose of ravulizumab.

Ultomiris_PatientAlertCard; Revised in December 2020

PATIENT ALERT CARD

Information for the Treating Doctor

This patient has been prescribed ravulizumab therapy, which increases the patient's susceptibility to meningococcal infection *(Neisseria meningitidis)* or other general infections.

- Meningococcal infections may become rapidly life-threatening or fatal if not recognised and treated early
- **Evaluate immediately if infection is suspected and treat with appropriate antibiotics if necessary**
- Contact prescribing doctor (below) as soon as possible
- Report Adverse Events via the national reporting systems below:

United Kingdom Yellow Card website **www.mhra.gov.uk/yellowcard**

Ireland HPRA Pharmacovigilance website **www.hpra.ie**

For more information about ravulizumab, please refer to the full Summary of Product Characteristics or e-mail: **medinfo.EMEA@alexion.com**

In case of safety concerns, call **0800 028 4394** in UK, **1800 882 840** in Ireland

Patients receiving ravulizumab should carry this card at all times. Show this card to any doctor involved in your health care.

Patient name _____

Parent/Guardian contact information _____

Hospital where treated _____

Unique Patient Identifier _____

Doctor name _____

Doctor's telephone number _____

PLEASE SHOW THE PATIENT ALERT CARD TO ANY HEALTHCARE PROFESSIONAL INVOLVED IN YOUR CHILD'S TREATMENT, SHOULD YOUR CHILD NEED MEDICAL ATTENTION.

PNH and aHUS REGISTRIES

To ensure that the care of people with paroxysmal nocturnal haemoglobinuria (PNH) and atypical haemolytic uremic syndrome (aHUS) continues to improve, it is important we have detailed information on the state of health and treatment of as many people with these conditions as possible. There are PNH and aHUS registry centres and your physician will provide further details about these registries. The aim of the **PNH and aHUS Registries** is to collect data to characterise and provide a better understanding of these diseases.

Your doctor may also ask you if you would like to participate in the **PNH or aHUS Registry** and will register you if you agree. If this happens you will receive more detailed information about it and be asked to sign a consent form to participate. You will be asked to complete a simple questionnaire about your health and well-being at the beginning and then every 6 months for the duration of the Registry. Your doctor will provide the Registry with some of your medical information such as diagnosis, treatment and medical history.

To include your data in the **PNH or aHUS Registry** your written permission is required. Your participation is entirely voluntary and any information that would allow you to be identified directly or indirectly will be removed so that it cannot be linked to you. Also, you can withdraw your permission at any time.

REPORTING SIDE EFFECTS

If your child experiences any side effects, talk to their doctor, pharmacist or nurse. This includes any possible side effects not listed in the patient information leaflet or this guide.

United Kingdom

Please report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme. You can report via:

- the Yellow Card website www.mhra.gov.uk/yellowcard
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours.

When reporting please provide as much information as possible. By reporting side effects, you can help provide more information on the safety of this medicine.

Ireland

In Ireland via HPRA Pharmacovigilance
Website: www.hpra.ie

REPORTING SIDE EFFECTS TO THE MANUFACTURER

By reporting side effects, you can help provide more information on the safety of this medicine.
You can report side effects to Alexion, please email: uk.adverseevents@alexion.com or, call:
UK: 0800 321 3902. Ireland: 1800 936 544

MORE INFORMATION

For more information about PNH or aHUS, visit: https://alexion.com/en/our-medicines/medicines/ultomiris
If you require further information on ravulizumab, please call or email Alexion Medical Information.
Email: medinfo.EMEA@alexion.com Tel: UK: 0800 028 4394 / Ireland: 1800 882 840

HOME HEALTHCARE SERVICE

Alexion funds a Home Healthcare service, which is available to all patients prescribed with ravulizumab.
For more details, please ask your physician about this service and availability.

REFERENCES

ULTOMIRIS® (ravulizumab) Patient Information Leaflet, available from:
https://www.medicines.org.uk/emc/ or https://www.medicines.ie/

Alexion Pharma UK Limited
3 Furzeground Way, Stockley Park, Uxbridge UB11 1EZ