

ULTOMIRIS[®] (ravulizumab) Parent/Legal Guardian Guide

Paroxysmal Nocturnal Hemoglobinuria (PNH)

Atypical Hemolytic Uremic Syndrome (aHUS)

▼ 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.

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1 INTRODUCTION

Ravulizumab is used to treat children with:

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

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

Ravulizumab must be prescribed by a doctor.

You will receive the following material from the doctor:

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

Your child's doctor will offer for your child to participate in the PNH/aHUS Registry. It is the doctor who can register your child in this registry. **This is only open to patients in Great Britain.**

2 IMPORTANT SAFETY INFORMATION FOR INFANTS AND CHILDREN WHO ARE TAKING RAVULIZUMAB

Risk of Meningococcal infection

- **Ravulizumab may reduce your child's natural resistance to a certain bacteria called *Neisseria meningitidis* that may increase your child's 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 ravulizumab

- ▶ Your child's doctor will vaccinate your child against meningococcal infection, at least 2 weeks before beginning therapy. If ravulizumab treatment is initiated less than 2 weeks after receiving meningococcal vaccine, the doctor will make sure that your child takes antibiotics to reduce the risk of infection until 2 weeks after your child has been vaccinated.
- ▶ Vaccination reduces the risk of developing meningococcal infection, but it does not remove the risk completely. Your child's doctor might consider that your child needs 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 child's doctor if you have any questions about the vaccinations your child requires before starting ravulizumab.

During treatment with ravulizumab:

- ▶ Be aware of the signs and symptoms of meningococcal infection and notify your child's doctor immediately if any of these occur.
- ▶ 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 may include:

- Severe muscle pain
- Severe headache
- Confusion
- Irritability

► **Carry the patient alert card at all times throughout the duration of your child's ravulizumab therapy and for 8 months after the last dose of ravulizumab and show it to any health care professional you see.**

If you cannot reach your child's doctor, seek IMMEDIATE emergency care at an emergency department and show them the patient alert card.

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.

Risk of other infections

- The 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.

REPORTING SIDE EFFECTS

If any side effects are experienced, please talk to a doctor, pharmacist, or nurse. This includes any possible side effects not listed in the patient information leaflet or this guide.

United Kingdom (Great Britain and Northern Ireland)

Please report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme. Reporting forms and information can be found at www.yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store.

Adverse events should also be reported to Alexion Pharma UK Ltd on uk.adverseevents@alexion.com or Freephone (UK): 0800 321 3902

Ireland

HPRA Pharmacovigilance

Website: www.hpra.ie

Adverse events should also be reported to Alexion Pharma UK Ltd on uk.adverseevents@alexion.com or Freephone (UK): 0800 321 3902

MORE INFORMATION

For more information about ravulizumab contact: medinfo.EMEA@alexion.com or Tel: UK: 0800 028 4394/ Ireland: 1800 882 840

HOME HEALTHCARE SERVICES

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

REFERENCES

1. ULTOMIRIS® (ravulizumab) Patient Information Leaflet, available here: <https://www.medicines.org.uk/emc/>, <https://www.emcmedicines.com/en-GB/northernireland/> or <https://www.medicines.ie/>