



ULTOMIRIS[®] (ravulizumab)

Guide for Patients/Parents/Caregivers

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1 INTRODUCTION

Ravulizumab is used to treat adults and children with:

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

Ravulizumab is also used to treat adults with:

- Generalized Myasthenia Gravis (**gMG**)
- Neuromyelitis Optica Spectrum Disorder (**NMOSD**)

Ravulizumab must be prescribed by a doctor.

You will receive the following material from your doctor:

- **Patient 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.
 - You must carry this card at all times throughout the duration of your ravulizumab therapy and for 8 months after the last dose of ravulizumab and show it to any healthcare professional you see.
- **Guide for Patients/Parents/Caregivers**
- **Ravulizumab Patient Information Leaflet**

2 SAFETY CONSIDERATIONS RELATED TO RAVULIZUMAB

Risk of Meningococcal infection

- Ravulizumab 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 disabilities².
- The patient must be vaccinated and revaccinated according to current national guidelines for vaccination use.

Before starting treatment with ravulizumab:

- ▶ Your doctor will vaccinate you against meningococcal infection, at least 2 weeks before beginning therapy. If ravulizumab 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 ravulizumab.

During treatment with ravulizumab:

- ▶ 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 sensitivity to light

- ▶ **You will be provided with a Patient Card. Please carry this with you at all times throughout the duration of your ravulizumab therapy and for 8 months after the last dose of ravulizumab 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 Ravulizumab

Risk of other infections

- Ravulizumab treatment may reduce your natural resistance to other similar bacterial infections including gonorrhea which is a sexually transmitted disease.
- Before starting ravulizumab, 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 ravulizumab therapy with caution to patients with active systemic infections.

Infusion/Allergic reactions

- Ravulizumab contains a protein, and proteins may cause infusion or allergic reactions (including anaphylaxis) in some patients.
- If you experience any signs or symptoms after receiving ravulizumab, you should consult your healthcare professional.

Blood abnormalities and cancers

- If you are a patient with PNH, you will be monitored for changes in blood cells.
- The PNH laboratory monitoring may potentially alert your doctor to blood abnormalities and cancers. The PNH laboratory monitoring continues during ravulizumab treatment and for a period not less than 16 weeks after ravulizumab is stopped.

Pregnancy and breast feeding

- Ravulizumab is not recommended during pregnancy and in women of childbearing potential not using contraception.
- Ask your doctor for advice before using ravulizumab if you are pregnant or breast-feeding, 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 ravulizumab treatment and up to 8 months after treatment.
- Male patients on ravulizumab should not father a child or donate sperm during treatment or up to 8 months after treatment.

3 HOW LONG WILL I NEED TO TAKE RAVULIZUMAB?

As you have a chronic disease, ravulizumab is intended to be an ongoing therapy.

Do not stop treatment without first discussing with your doctor.

If you stop using ravulizumab for PNH

Interrupting or stopping treatment with ravulizumab may cause your PNH symptoms to come back more severely.

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 ravulizumab 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 (anaemia),
- Dark urine,
- Fatigue,
- Abdominal pain,
- Shortness of breath,
- Difficulty swallowing,
- Impotence (erectile dysfunction),
- Confusion or change in how alert you are,
- Chest pain, or angina,
- Problems with your kidneys (an increase in your serum creatinine level) or
- Blood clotting (thrombosis).

If you have any of the above contact your doctor.

If you stop using ravulizumab for aHUS

Interrupting or ending treatment with ravulizumab 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 ravulizumab 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.

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

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

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

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.

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.

Ireland

Health Products Regulatory Authority (HPRA)

Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Ireland, D02 XP77

Reporting forms and information can be found at www.hpra.ie, or email: medsafety@hpra.ie.

Adverse events should also be reported to Alexion Pharma UK Ltd via contactazmedical.astrazeneca.com. Alternatively, if this form is unavailable, Adverse events can be reported to patient-safety-ireland@astrazeneca.com or Tel: 1 800 936 544

MORE INFORMATION

For more information about ravulizumab contact: medinfo.EMEA@alexion.com

or Freephone: 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. Ravulizumab SmPC, available here: www.medicines.ie and www.hpra.ie

