PATIENT ALERT CARD





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 <u>immediately call your doctor or seek emergency medical care</u>, <u>preferably in a major emergency medical care centre</u>:

- 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.

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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
- Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at www.medicinesauthority.gov.mt/ adrportal, and sent by post or email to; P: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann SGN 3000 E:

postlicensing.medicinesauthority@gov.mt

For more information about ravulizumab, please refer to the Patient Information Leaflet (www.ema.europa.eu) or e-mail: medinfo.EMEA@alexion.com



Patients receiving ravulizumab should carry this card at all times

| Sh | ow this card to any doctor involved in your health care. | |
|-------------------------------------|--|--|
| Patient name | | |
| Parent/Guardian contact information | | |
| Hospital where treated | | |
| Unique Pa | nique Patient Identifier | |
| Doctor name | | |
| Doctor's telephone number | | |