

Important Safety Information for patients having crovalimab (**PiaSky**)

Patient Card

Show this card to any Healthcare Professional involved in your care

“This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA.”

▼ 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. See final page for details on how to report.

Information for the patient

You have been prescribed crovalimab as treatment for paroxysmal nocturnal haemoglobinuria (PNH). For more information on crovalimab, refer to the crovalimab Patient Information Leaflet.

Crovalimab may make you less able to fight infections, especially meningococcal infections, which require immediate emergency medical attention.

Immediately seek emergency medical attention if you have the following symptoms of possible meningococcal infection:

- Fever
- Feeling sick (nausea or vomiting)
- Headaches
- Confusion or irritability
- Stiff neck or back
- Muscle aches with flu-like symptoms
- Sensitivity of the eyes to light
- Skin rashes or spots

Meningococcal infections may become rapidly life-threatening or fatal if not recognised and treated early.

Crovalimab may cause severe allergic reactions.

Immediately seek emergency medical attention if you have the following symptoms of possible severe allergic reaction:

- Tight chest or wheezing,
- Feeling short of breath,
- Fever or chills
- Severe dizziness, or light headedness
- Swelling of the lips, tongue, face
- Skin itching, hives, or rash

Always keep this card with you during treatment and for 11 months after your last crovalimab dose. Your risk of meningococcal infection may continue for several months after your last dose of crovalimab.

Show this card to any doctor, nurse or pharmacist involved in your care and if you go to hospital.

Information for the treating doctor

This patient has been prescribed Crovalimab, a complement C5 inhibitor, which may make them more susceptible to meningococcal infection

- Meningococcal infections may become rapidly life threatening or fatal if not recognised and treated early
- Evaluate immediately if infection is suspected and treat as appropriate
- **Contact the prescribing doctor (below)** as soon as possible
- Report Adverse Events via SFDA and MAH reporting information
- Company contact point – Call:



The National Pharmacovigilance Centre (NPC)
Land Line: 19999.
Web-page: <http://ade.sfda.gov.sa>
Email: npc.drug@sfda.gov.sa



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Contact Information

Patient Name:

Patient/Parent/Guardian contact information:

Hospital where treated with crovalimab:

Unique patient identifier:

Treating doctor (prescriber)

Name:

Contact number: