Reporting of side effects

▼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. If you experience any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the Package Leaflet. You can also report side effects directly (see details below).

Please report side effects to:
The Drug Surveillance Centre,
Roche Products (Ireland) Limited,
3030 Lake Drive, Citywest Business Campus,
Dublin 24, D24 KX6Y, Ireland
Telephone: (01) 4690700
Email: ireland.drug_surveillance_centre@roche.com

Or report to:
HPRA Pharmacovigilance
Website: www.hpra.ie

Further Information

Talk to your doctor, nurse or pharmacist if you have any questions or concerns.

Contact Information

Patient name:

.....

Patient/Parent/Guardian contact information:

.....

Hospital where treated with crovalimab:

.....

Treating doctor (prescriber) name:

.....

Treating doctor (prescriber) contact number:

.....

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FOR USE IN IRELAND

Important Safety Information for patients receiving **Piasky▼ (crovalimab)** **Patient Card**

▼ 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. See box overleaf for details on how to report side effects.

Show this card to any Healthcare Professional involved in your care.

- Carry this card with you at all times during treatment and for 11 months after your last dose of crovalimab

Please read this material along with the Package Leaflet supplied with this medicine or also available on www.hpra.ie or www.medicines.ie before taking this medicine.

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, accessible at www.hpra.ie or www.medicines.ie.

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)
- Vomiting
- Headaches
- Confusion or irritability
- Stiff neck or back
- Muscle aches with flu-like signs or 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 after crovalimab administration:

- 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

If you have had an allergic reaction, you should confirm with your doctor or nurse if crovalimab treatment should continue or not.

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 Piasky (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
- Check for any symptoms of injection- and infusion-related reactions including severe allergic reactions