FOR USE IN IRELAND

Healthcare Professional Guide

Piasky▼(crovalimab)

This guide provides important safety information to assist in your understanding of the benefits and risks associated with Piasky (crovalimab)

▼ 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 page 7 for details on how to report.

This is additional risk minimisation material and is provided by Roche Products (Ireland) Limited as a condition of the crovalimab marketing authorisation.

This material should be read in conjunction with the Summary of Product Characteristics (SmPC) which is available on www.medicines.ie and www.hpra.ie

IE Version 2.0.4
M-IE-00001989
Date of preparation: April 2026
Date of HPRA approval: April 2026

How to use this guide

This guide is intended to enhance healthcare professionals' awareness of safety risks associated with crovalimab, including meningococcal infections, serious infections and serious haemolysis after crovalimab discontinuation and to provide information about associated prevention measures, detection, monitoring and/or proper management.

What is Crovalimab?

Crovalimab is a recombinant humanised immunoglobulin G1 (IgG1) monoclonal antibody that specifically binds to complement protein 5 (C5) and causes inhibition of terminal complement activity. In patients with paroxysmal nocturnal haemoglobinuria (PNH), this medicine inhibits terminal complement-mediated intravascular haemolysis.

Safety risks

Meningococcal infection

Due to its mechanism of action, the use of crovalimab may increase the patient's susceptibility to meningococcal infections (septicaemia and/or meningitis). Meningococcal infections may become rapidly life-threatening or fatal if not recognised and treated early. To reduce the risk of meningococcal infection, all patients must be vaccinated with a tetravalent meningococcal vaccine.

Key actions required:

Prior to treatment:

Vaccinate your patients with a tetravalent meningococcal vaccine (against serogroups A, C, Y, W135), and serogroup B where available locally, at least 2 weeks prior to initiating crovalimab.

- Provide the Patient/Caregiver Guide to patients/caregivers. Explain the guide to them to increase their awareness of potential meningococcal infections occurring and the relevant signs and symptoms they may experience which include:
  - Fever
  - Feeling sick (nausea)
  - 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
- Provide the Patient Card to patients/caregivers of patients being treated with crovalimab and explain that they must always carry it while receiving this medicine treatment and for 11 months after their last crovalimab dose.
- Inform patients that if they have any signs or symptoms of infection, they should go to the emergency room immediately and show the emergency room staff their Patient Card.
- Provide the Patient Information Leaflet to patients/caregivers.

During treatment/monitoring:

- If patients initiate crovalimab treatment less than 2 weeks after receiving vaccination, or receive vaccination after starting crovalimab, then you should prescribe prophylactic antibiotics from the time they start crovalimab until 2 weeks after vaccination.
- Vaccination alone may not be sufficient to prevent meningococcal infection. In addition, you should consider administering antibacterial agents during treatment with this medicine based on local guidelines.
- Revaccinate patients according to the current national vaccination guidelines for vaccine use.
- Counsel the patients on side effects of vaccination. Inform patients that vaccination or revaccination may further activate the complement system and, as a result, patients with complement mediated diseases may experience increased signs and symptoms of their underlying disease.
- Monitor your patients for early signs of meningococcal infections, evaluate immediately if infection is suspected, and treat as appropriate in accordance with local guidelines.

Other systemic infections

Patients were excluded from clinical studies with this medicine if they had any active systemic bacterial, viral, or fungal infection within 14 days prior to starting treatment.

Due to its mechanism of action, crovalimab must be administered with caution to patients with active systemic infections. If this medicine is administered to patients with active systemic infections, patients should be monitored closely for signs and symptoms of worsening infection.

Inform patients that they may have increased susceptibility to infections with *Neisseria* spp. and other encapsulated bacteria. Vaccinations for the prevention of *Streptococcus pneumoniae* and *Haemophilus influenzae* type b (Hib) infections should be administered according to local guidelines.

Serious haemolysis after crovalimab discontinuation

If patients discontinue crovalimab and do not initiate another therapy, you must monitor them closely for signs and symptoms of serious intravascular haemolysis, identified by:

- elevated lactate dehydrogenase levels
- sudden decrease in PNH clone size or haemoglobin
- re-appearance of symptoms such as:
  - fatigue
  - haemoglobinuria
  - abdominal pain
  - shortness of breath (dyspnoea)
  - major adverse vascular events (including thrombosis)
  - dysphagia
  - erectile dysfunction

If signs and symptoms of haemolysis occur after discontinuation, including elevated LDH, consider restarting appropriate treatment.

You should tell your patients that they must discuss with you discontinuing or postponing crovalimab treatment.

Patient Card

Provide a Patient Card to patients/caregivers being treated with crovalimab and explain that they must always carry it while on crovalimab treatment and for 11 months after their last dose.

Inform patients/caregivers of patients being treated with crovalimab that if they have symptoms of meningococcal infection or severe allergic reaction, they should go to the emergency department immediately and show the emergency department staff the Patient Card.

Reporting adverse drug reactions

Reporting of suspected adverse events or reactions

▼ 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 details below). Reporting suspected adverse events or reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Where possible, healthcare professionals should report adverse events or reactions by brand name and batch number.

In the event of a suspected adverse event, please report it 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

Alternatively, suspected adverse reactions should be reported to:
HPRA Pharmacovigilance
Website: www.hpra.ie

For a full list of side effects, refer to the SmPC available on www.medicine.ie and www.hpra.ie

By reporting side effects, you can help provide more information on the safety of this medicine.

Further information

Additional copies of the materials can be downloaded from the HPRA website (enter '<Piasky>' under 'Find a Medicine' and click 'EdM' under the 'Documents' column). Alternatively if you would like hard copies, please contact Roche Products (Ireland) Limited, 3030 Lake Drive, Citywest Business Campus, Dublin 24, D24 KX6Y, Ireland by mail, telephone (01 4690700) or email (ireland.drug_surveillance_centre@roche.com).

For further information about this medicine, please contact Medical Information at Roche Products (Ireland) Limited by telephone (01 4690700) or email (Ireland.druginfo@roche.com).

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