FOR USE IN IRELAND

Patient/Caregiver Guide to Piasky▼ (crovalimab)

▼ 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 on page 10 for how to report side effects.

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

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How to use this guide

This guide has been given to you because you, or someone in your care has been prescribed crovalimab. This guide is intended to increase patients´ or their caregivers (such as parents, legal guardians, and other caregivers) awareness of safety risks associated with this medicine, including:

- Increased risk of infections, in particular by the bacteria *Neisseria meningitides* (meningitis infection) and other serious infections.
- Infusion- and injection-related reactions.
- Serious haemolysis (breakdown of red blood cells in blood vessels) after crovalimab discontinuation.

You or the person in your care may not experience side effects. However, this information is to help you or the person in your care identify signs of a side effect early, and to seek medical assistance when needed.

Key information

Read this guide and make sure you understand the information. If you or your caregiver have any questions, speak to your doctor, nurse or pharmacist.

Your doctor or nurse will provide you with a Patient Card containing information about the key signs and symptoms of meningococcal infections and severe allergic reactions. You must always carry the Patient Card with you while on crovalimab treatment and for 11 months after the last dose of this medicine.

This guide is intended for information only and should complement (not replace) the Patient Information Leaflet that is packaged with your medication. For a complete list of side effects and other important information, please refer to the Patient Information Leaflet available at www.hpra.ie and www.medicines.ie.

What is Piasky?

Piasky contains the active substance crovalimab. It belongs to a class of medicines called ‘monoclonal antibodies’, which are proteins that are designed to attach to a specific target in the body. This medicine was developed to specifically bind to a protein called complement protein 5 (C5) and inhibits its activity.

Crovalimab is provided as a liquid solution that is given either as an infusion into your vein (intravenous infusion) or an injection under your skin (subcutaneous injection). This medicine is used to treat a disease called paroxysmal nocturnal haemoglobinuria (PNH).

Side effects

The important side effects potentially associated with crovalimab are listed below. There may be additional side effects that are not known at this time.

Increased risk of infections, in particular by the bacteria *Neisseria meningitidis*

Treatment with crovalimab may increase your risk of infections, in particular by the bacteria *Neisseria meningitidis*. Infections with *Neisseria meningitidis*, also known as meningococcal infections, may quickly become life-threatening or fatal, especially if not recognised and treated early. Meningococcal infections includes serious infections such as septicaemia (blood poisoning) and meningitis (inflammation of the membranes that surround the brain and spinal cord).

Tell your doctor straight away if you have any of the following, which may be signs of a meningococcal infection. If you cannot contact your doctor, you should go to the emergency department and show the emergency department staff your Patient Card:

- 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

Increased risk of other serious infections

- Crovalimab may also increase your risk of other serious infections, such as infections caused by *Streptococcus pneumoniae* and *Haemophilus influenzae*.

- Tell your pharmacist or doctor if you have any of the following, which may be signs of an infection. If you cannot contact your pharmacist or doctor, you should go to the emergency department and show the emergency department staff your Patient Card:

  - Fever
  - Cough
  - Chest pain
  - Tiredness
  - Feeling short of breath
  - Painful rash
  - Sore throat
  - Burning pain when passing urine
  - Feeling weak or generally unwell

Vaccination to reduce the risk of meningococcal infections and other serious infections

To reduce the risk for meningococcal infections, you need to be vaccinated against the bacteria *Neisseria meningitidis*. If you have not been vaccinated before, or your vaccination was too long ago so that protection is not effective anymore, your doctor will ensure that you receive a vaccination against *Neisseria meningitidis* prior to starting treatment with this medicine. As a result of vaccination, you may temporarily experience increased symptoms of your disease.

This vaccination should be given at least 2 weeks before starting crovalimab. If you cannot be vaccinated at least 2 weeks before starting this medicine, then your doctor will prescribe antibiotics (medications to treat bacterial infections) to reduce the risk of infection, from the time you start crovalimab until 2 weeks after vaccination.

Your doctor or pharmacist will receive annual vaccination reminders and will contact you in case you need revaccination. It is important that your vaccinations are up to date, so speak with your doctor or nurse about this.

You should be aware that the meningococcal vaccination reduces the risk of infections but does not completely eliminate this risk. Your doctor may prescribe antibiotics for a prolonged time to prevent the infection.

In addition to vaccination against meningococcal infection, your doctor may also require you are vaccinated against *Streptococcus pneumoniae* and *Haemophilus influenzae* type b (Hib) infections according to local guidelines.

Infusion- and injection-related reactions

Infusion- and injection-related reactions are risks associated with any drug administered intravenously (into the vein) or subcutaneously (under the skin).

When crovalimab is administered as an intravenous infusion (into the vein) or subcutaneous injection (under the skin), you may experience reactions. Inform your doctor or nurse immediately if you notice any of the following signs, which could indicate a reaction to the infusion or injection:

- Headache
- Lower back pain
- Pain at infusion site and elsewhere
- Swelling
- Bruising or bleeding
- Red skin
- Itching and rash

Severe allergic reactions

You may have an allergic reaction to the infusion or injection. Tell your doctor or nurse straight away if you experience any of the following symptoms which may be signs of an infusion or injection reaction. If you cannot contact your doctor or nurse, go to the emergency department and show the emergency department staff your Patient Card:

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

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

Treatment discontinuation

If you stop taking crovalimab and do not switch to another treatment for PNH, tell your doctor immediately if you develop symptoms that are signs of intravascular haemolysis (breakdown of red blood cells in blood vessels) including:

- Symptoms of anaemia (low levels of red blood cells), such as feeling tired or having low energy and dark urine
- Belly pain
- Difficulty swallowing
- Difficulty getting or keeping an erection (erectile dysfunction)
- Blood clots, with symptoms such as progressive swelling in one leg or breathlessness when not performing strenuous activities
- The kidneys not working properly

What to do if you experience any side effects

If you have any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the Patient Information Leaflet.

Reporting of side effects

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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

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

Further information

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

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