PiaSky® ▼
(crovalimab)

Patient/Caregiver Guide

Important Safety Information for patients prescribed crovalimab or for whom the prescribing decision has been made

▼ *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 get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet.

Please report side effects to the MHRA through the Yellow Card scheme. You can report via:
• the Yellow Card website www.mhra.gov.uk/yellowcard
• the free Yellow Card app available from the Apple App Store or Google Play Store
Alternatively you can report a side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours. When reporting please provide as much information as possible. By reporting side effects, you can help provide more information on the safety of this medicine.

You should also report side effects to Roche Products Ltd by emailing the Roche Drug Safety Centre at welwyn.uk_dsc@roche.com or calling +44 (0) 1707 367554.

This educational material is provided by Roche Products Limited and is mandatory as a condition of the Marketing Authorisation in order to further minimise important selected risks.

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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 crovalimab, including increased risk of infections, in particular by the bacteria *Neisseria meningitidis* (meningococcal infections), infusion and injection-related reactions, and serious damage to, and breakdown of your red blood cells (haemolysis) 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/advice as soon as possible.

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 will give you a Patient Card that says you are at an increased risk of meningococcal infections. You must always carry the Patient Card with you while on crovalimab treatment and for 11 months after the last crovalimab dose
- Crovalimab will be supplied through a Controlled Access Programme. Ask your doctor or nurse to also add your Controlled Access Programme ID (or CAP ID) to your Patient Card, because your pharmacist may ask for it

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 (please see final page for further details), or alternatively, ask your healthcare professional for a copy of the Summary of Product Characteristics (SmPC).

What is crovalimab?

Crovalimab is an antibody. An antibody is a large protein that is normally produced by your body's immune system to identify and neutralise foreign objects, such as bacteria and viruses. Crovalimab was developed to specifically attach to a protein called complement component 5 (C5), which is a part of the body's defence system called the 'complement system', and block its activity.

Crovalimab is provided in a liquid solution that is given either as an infusion into your vein or an injection under your skin. These are called intravenous infusion and subcutaneous injection, respectively.

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. If you have any side effects, talk to your doctor. This includes any possible side effects not listed in the Patient Information Leaflet that is packaged with your medication.

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

The use of crovalimab targets the complement system, which is part of the body's defences against infection. 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 recognized and treated early.

You should immediately seek medical attention if you experience any of the following symptoms, which may be signs of a meningococcal infection during treatment with crovalimab. Go to Accident and Emergency (A & E) immediately and show the A & E staff your Patient Card.

- 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

Vaccination to reduce risk of meningococcal 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 to provide sufficient protection, your doctor will ensure that you receive a vaccination against *Neisseria meningitidis* prior to starting crovalimab treatment. 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 crovalimab, 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.

Crovalimab will only be supplied if your doctor submits proof that you are receiving the required vaccination and/or antibiotics. 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 in order 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

Risks associated with any drug given by intravenous (into the vein) and subcutaneous (under the skin) administration are infusion and injection-related reactions.

There is a risk that you may suffer a severe allergic reaction. You should seek immediate medical attention if you experience any of the following symptoms, which may be signs of infusion or injection-related reactions during treatment with crovalimab. Go to A & E and show the A & E 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

Treatment discontinuation

- Do not stop treatment with crovalimab without discussing it with your doctor
- Do not postpone your crovalimab treatment without discussing it with your doctor
- If you stop treatment with crovalimab and you do not start an alternative treatment to control your PNH, your doctor will monitor you for signs and symptoms of red blood cell breakdown (haemolysis) and worsening of your disease, such as:
  - Tiredness (fatigue)
  - Dark urine (haemoglobinuria)
  - Stomach (abdominal) pain
  - Feeling short of breath (when not performing strenuous activities)
  - Blood clots (throbbing or cramping pain, swelling, redness, and warmth in a leg or arm)
  - Swallowing difficulties
  - Erectile dysfunction

PNH Registry

Your doctor will inform you about the registry and how you can participate. The data collection will be via the International PNH Interest Group (IPIG) Registry. Your participation is entirely voluntary and information that would allow direct or indirect identification of you will be removed. In addition, you can withdraw permission to be involved in the registry at any time.

Further sources of information

For full details, refer to the PiaSky Patient Information Leaflet. This can also be accessed at: www.medicines.org.uk/emc if based in Great Britain or www.emcmedicines.com/en-gb/northernireland if based in Northern Ireland.

Notes

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