Your guide to crovalimab (PiaSky)

"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.

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,* infusion and injection-related reactions, and serious damage to, and breakdown of your red blood cells (hemolysis) 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 crovalimab dose.

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, 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 neutralize foreign objects, such as bacteria and viruses. Crovalimab was developed to specifically bind to a protein called complement protein 5 (C5) which is a part of the body's defence system called the complement system, and block its activity.

Crovalimab is provided as 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.

1 - 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 recognised and treated early.

You should immediately seek medical attention if you experience any of the following symptoms during treatment with crovalimab. Go to the emergency room and show the emergency room 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 the 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 so that protection is not effective anymore, 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.

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.

2 **- Infusion- and injection-related reactions**

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

In very rare cases, you could suffer a severe allergic reaction. You should immediately seek medical attention if you experience any of the following symptoms. Go to the emergency room and show the emergency room 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 treatment with another treatment to control your PNH, your doctor will monitor you for signs and symptoms of red blood cell breakdown (hemolysis) and worsening of your disease, such as:

- Tiredness (fatigue)
- Dark urine (hemoglobinuria)
- Stomach (abdominal) pain
- Feeling short of breath
- Major adverse vascular events (throbbing or cramping pain, swelling, redness and warmth in a leg or arm)
- Swallowing difficulties
- Erectile dysfunction

What to do if you experience any side effects

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

For a full list of side effects, refer to the attached Package Leaflet.

You can also report side effects directly via the national reporting system

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

Roche Products Saudi Arabia L.L.C.
Direct Tel.: +966 12 211 4600
Mobile: +966 56 784 4692
Email: jeddah.drug_safety@roche.com

"▼ 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."

COMPANY CONTACT POINT

Should you have any questions regarding the use of Piasky®, please feel free to contact us at *jeddah.medinfo@roche.com*