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Summary report on authorisation dated 16 June 2025

Piasky® (active substance: crovalimab)

Authorisation in Switzerland: 13 February 2025

Solution for injection/infusion for the treatment of adults and adolescents aged 12 years or older with paroxysmal nocturnal haemoglobinuria

About the medicinal product

Piasky, containing the active substance crovalimab, is used for the treatment of paroxysmal nocturnal haemoglobinuria (PNH) in adults and adolescents aged 12 years or older and weighing 40 kg or more. Piasky is used in patients with haemolysis (breakdown of red blood cells) and clinical symptoms indicating high disease activity, and patients whose disease is clinically stable after treatment with a C5 inhibitor for at least the past six months.

In patients with PNH, the body's own defence system (complement system) is overactive and attacks their red blood cells. This can result in anaemia, fatigue, functional impairments, stomach pain, dark urine, shortness of breath, difficulty swallowing, erectile dysfunction, and the formation of blood clots.

Since PNH is a rare and life-threatening disease, the medicinal product Piasky has been authorised as an orphan drug. The term "orphan drug" is used to refer to important medicines for rare diseases.

Mode of action

Piasky contains the active substance crovalimab, a monoclonal antibody (an immunologically active protein) that acts on the complement system, which forms part of our immune system, i.e. our defence system. In PNH, this complement system wrongly attacks the body's own red blood cells. Crovalimab acts as a C5 inhibitor, which means that crovalimab binds to the complement 5 (C5) protein and blocks its activation. As a result, the breakdown of the red blood cells is reduced, thereby helping to alleviate the symptoms of PNH and reducing the number of blood transfusions required.

Administration

Piasky is a prescription-only medicine.

Piasky is administered as an intravenous infusion and an injection under the skin (subcutaneously). The starting dose is given as an infusion into the vein on the first day, followed by four weekly subcutaneous injections on days 2, 8, 15 and 22. From day 29, a maintenance dose is administered subcutaneously every 4 weeks. The exact dosage is based on the patient's weight. Piasky should be administered under the supervision of a doctor experienced in the treatment of haematological disorders.

Efficacy

The efficacy of Piasky was investigated in the study named COMMODORE 2. In this study, Piasky was compared with the authorised active substance eculizumab. The study included PNH patients who had not previously been treated with another complement inhibitor. The primary treatment period was 24 weeks, followed by an extension phase during which patients could continue to receive treatment with Piasky or switch to Piasky. There were two main study endpoints: the proportion of patients who did not need any blood transfusions up to week 25, and haemolysis control (measured by the LDH level, a marker for the destruction of red blood cells) from week 5 to week 25. The results showed that Piasky was not inferior to eculizumab in either of these endpoints.

Precautions, undesirable effects, & risks

Piasky must not be used in those who are hypersensitive to the active substance or any of the excipients.

Piasky can increase the risk of severe infections, particularly infections caused by meningococci and other encapsulated bacteria. Since meningococcal infections are particularly dangerous and can rapidly lead to serious health complications, it is important for patients to be vaccinated against meningococci before starting the treatment with Piasky. Patients receiving Piasky should immediately seek medical advice if they experience symptoms such as fever, nausea, stiff neck or rash.

The most common side effects of Piasky are type III immune complex reactions (a specific type of hypersensitivity reaction), which can occur after switching from another complement 5 inhibitor, as well as upper respiratory tract infections, headache, fever, and reactions to infusions.

All precautions, risks, and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

There is a need for the medicinal product Piasky since PNH is a rare, but serious and potentially life-threatening disease, for which limited treatment options exist. Piasky offers a new treatment option for these patients and has proved to be effective in clinical trials by controlling haemolysis and reducing the need for blood transfusions. Taking all the risks and precautions into account, and based on the available data, the benefits of Piasky outweigh the risks. Swissmedic has therefore authorised the medicinal product Piasky, containing the active substance crovalimab, for use in Switzerland.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Piasky®

Information for patients (package leaflet): Information for patients Piasky®
Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.