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Piasky (*crovalimab*)

An overview of Piasky and why it is authorised in the EU

What is Piasky and what is it used for?

Piasky is a medicine to treat adults and children over 12 years of age weighing 40 kg or more who have paroxysmal nocturnal haemoglobinuria (PNH).

PNH is a disease in which excessive haemolysis (the breakdown of red blood cells) results in anaemia (low levels of haemoglobin, the protein in red blood cells that carries oxygen around the body), thrombosis (blood clots in blood vessels), pancytopenia (low levels of blood cells) and dark urine (due to large amounts of haemoglobin being released into the urine).

Piasky is used in patients with haemolysis and symptoms of high disease activity, and in patients who have been stable on treatment with a C5 inhibitor (another medicine used to treat PNH) for at least 6 months.

Piasky contains the active substance crovalimab.

How is Piasky used?

The medicine can only be obtained with a prescription and treatment should be started by a doctor experienced in the management of patients with blood-related disorders.

The first dose of Piasky is given as an infusion (drip) into a vein. After that, the medicine is given as an injection under the skin once a week for the first 4 weeks and once every four weeks thereafter. After receiving adequate training, patients may inject the medicine at home without medical supervision.

Piasky is intended for long-term use unless the patient develops serious side effects.

For more information about using Piasky, see the package leaflet or contact your doctor or pharmacist.

How does Piasky work?

The active substance in Piasky, crovalimab, is a monoclonal antibody (a type of protein) that has been designed to attach to the C5 complement protein, which is a part of the body's defence system called the 'complement system'.

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In patients with PNH, the complement proteins are over-active and damage the patients' own cells. By blocking C5, crovalimab prevents complement proteins from damaging cells, especially red blood cells, thereby helping to relieve the symptoms of the disease.

What benefits of Piasky have been shown in studies?

In a main study involving 204 adult patients with PNH who were not previously treated with a complement inhibitor, Piasky was as effective as eculizumab (another medicine for PNH) at controlling haemolysis and reducing the need for blood transfusions.

After 24 weeks of treatment, around 79% of patients given Piasky were able to achieve control of haemolysis, as measured by the blood level of the enzyme lactate dehydrogenase (LDH) which reflects the breakdown of red blood cells; in patients given eculizumab, this was also around 79%. In addition, 66% (88 out of 134) of patients given Piasky and 68% (47 out of 69) of patients given eculizumab did not need a blood transfusion to increase the level of their red blood cells.

These results were also seen in a small group of 6 children with PNH who were given Piasky.

What are the risks associated with Piasky?

For the full list of side effects and restrictions with Piasky, see the package leaflet.

The most common side effects (which may affect more than 1 in 10 people) include type III immune complex mediated reactions (an abnormal immune reaction where antibodies attach to the medicine and form clusters that collect in body tissues, causing symptoms that include fever, joint pain, itching and rash) in patients who switched from treatment with another C5 inhibitor to Piasky, upper respiratory tract (nose and throat) infection, fever, headache and infusion-related reactions.

The most serious side effects (which may affect up to 1 in 10 people) include type III immune complex mediated reaction in patients who switched from treatment with another C5 inhibitor to Piasky and pneumonia (lung infection).

Based on how Piasky works, it may increase the risk of infections, including meningococcal sepsis. Piasky must not be given to people who have an infection caused by *Neisseria meningitides*; it must also not be given to patients who have not been vaccinated against this bacterium unless they have planned the vaccination and take appropriate antibiotics to reduce the risk of infection until the vaccination and for two weeks thereafter.

Why is Piasky authorised in the EU?

People with PNH need lifelong treatment for their symptoms. Piasky provides an additional treatment option which, after the first 4 weeks of treatment, only needs to be taken once every 4 weeks and can be self-injected at home. Piasky's benefits were shown to be comparable to another C5 inhibitor in terms of controlling haemolysis and reducing the need for blood transfusions. Its safety profile is considered manageable considering the measures in place to minimise the risks. In patients who switch to Piasky from other C5 inhibitors, type III immune complex reactions are an expected risk that should be considered. The European Medicines Agency therefore decided that Piasky's benefits are greater than its risks and that it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Piasky?

The company that markets Piasky will ensure that prescription of the medicine occurs only after checking that the patient has been vaccinated against *N. meningitides* and will send reminders to prescribers and pharmacists to check if any further vaccination is needed for patients taking Piasky. The company will also provide doctors and patients with educational materials on the risk of infections caused by meningococcal bacteria, the need for vaccination and the risk of serious haemolysis after stopping treatment. Additionally, patients will be given a card they should always carry with them with information about the key signs and symptoms of meningococcal infections and severe allergic reactions, and instructions about when to seek emergency medical care.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Piasky have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Piasky are continuously monitored. Suspected side effects reported with Piasky are carefully evaluated and any necessary action taken to protect patients.

Other information about Piasky

Piasky received a marketing authorisation valid throughout the EU on 22 August 2024.

Further information on Piasky can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/piasky.

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