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Public Summary SwissPAR dated 10 July 2023

# Aspaveli® (active substance: pegcetacoplan)

First authorisation in Switzerland: 23 March 2023

Medicinal product (solution for infusion) for the treatment of adults with paroxysmal nocturnal haemoglobinuria (PNH)

## Information on authorisation

The medicinal product Aspaveli contains the active substance pegcetacoplan and is administered as a subcutaneous infusion.

Aspaveli is used to treat nocturnal haemoglobinuria (PNH) in adults who have an inadequate response to treatment with another type of medicinal product for PNH, known as a C5 inhibitor.

In patients with PNH, the body's own defence system (complement system) is overactive and attacks the 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.

Aspaveli was developed to bind the complement protein C3, which forms part of the complement system. By binding to and blocking the C3 protein, Aspaveli can prevent the complement system from attacking red blood cells, thereby bringing the symptoms of the disease under control.

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

In deciding whether to authorise the medicinal product Aspaveli, containing the active substance pegcetacoplan, Swissmedic took into account the assessments of the European Medicines Agency (EMA) and the S Food and Drug Administration (FDA) as well as the corresponding product information.

Since the assessment of the clinical data was based on the assessment reports of foreign authorities, the preconditions for a SwissPAR (Swiss Public Assessment Report) and a resulting Public Summary SwissPAR are not fully met. Swissmedic refers to the authorisations of the foreign reference authorities.

www.ema.europa.eu

www.fda.gov

## Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Aspaveli®

Information for patients: Patient information Aspaveli®

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 in the Public Summary SwissPAR.

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.