swissmedic

Summary report on authorisation dated 3 June 2025

Aspaveli® (active substance: pegcetacoplan)

Indication extension in Switzerland: 03.02.2025

Solution for infusion for the treatment of adults with paroxysmal nocturnal haemoglobinuria (PNH) who have anaemia as a result of this disease

About the medicinal product

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

Aspaveli is used to treat adults with paroxysmal nocturnal haemoglobinuria (PNH) who have anaemia as a result of this disease.

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 (e.g. of the kidneys), stomach pain, dark urine, shortness of breath, difficulty swallowing, erectile dysfunction, and the formation of blood clots.

Aspaveli was first authorised by Swissmedic on 23 March 2023 for the treatment of adults with paroxysmal nocturnal haemoglobinuria (PNH) who have an inadequate response to treatment with another type of medicinal product for PNH, known as a C5 inhibitor.

With this indication extension, Aspaveli can now also be used for patients with PNH who have not received any previous treatment.

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

This indication extension for Aspaveli has been authorised by Swissmedic under Article 13 of the Therapeutic Products Act (TPA). This means that the medicinal product is already authorised in another country with comparable medicinal product control.
In this case, Swissmedic takes into consideration the results of checks carried out by foreign regulatory agencies, provided certain requirements are fulfilled. These involve checks on the quality, efficacy, and safety of the medicinal product, and the extent to which the results can be accepted for Switzerland. The consideration of the results of foreign authorisation procedures is intended to help ensure that medicines that are already authorised abroad can be made available to patients in Switzerland as quickly as possible.

In deciding whether to authorise the indication extension for Aspaveli in Switzerland, Swissmedic accepted the assessment and approval decision of the European Medicines Agency (EMA) (EMEA/H/C/005553/II/0011)

and has only conducted a limited scientific review.
Since the assessment of the clinical data was based on the assessment report of a foreign partner authority, the preconditions for a full SwissPAR (Swiss Public Assessment Report) and a resulting Summary report on authorisation are not met. Swissmedic refers to the authorisation of the foreign comparator product.

www.ema.europa.eu

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 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.