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Summary report on authorisation dated 23 March 2026

Aspaveli® (active substance: pegcetacoplan)

Indication extension in Switzerland: 4 December 2025

Solution for infusion for the treatment of adults and adolescents (12–17 years) with C3 glomerulopathy (C3G) or primary immune complex membranoproliferative glomerulonephritis (IC-MPGN)

About the medicinal product

Aspaveli contains the active substance pegcetacoplan.

Aspaveli was first authorised in Switzerland on 23 March 2023 for the treatment of paroxysmal nocturnal haemoglobinuria (PNH) in adults.

This indication extension means that Aspaveli can now also be used for the treatment of adult and adolescent patients aged 12 years and over with C3 glomerulopathy (C3G) or primary IC-MPGN.

These rare renal diseases are caused by dysregulation of the complement system, part of the natural defence system which usually fights pathogens. In C3G and IC-MPGN, this defence system is overactive and attacks parts of the kidneys, which can result in inflammation and a loss of protein via the urine (proteinuria).

Since these are rare and life-threatening diseases, the medicine has been authorised as an orphan drug. "Orphan drug" is a designation given to medicinal products for rare diseases.

Mode of action

Pegcetacoplan, the active substance in Aspaveli, blocks the complement protein C3, a key molecule in the immune system. Blocking C3 regulates overactivation of the complement system, which helps to reduce the accumulation of C3 breakdown products in the kidneys and stabilise renal function.

Administration

Aspaveli is a prescription-only medicine and is administered twice weekly via subcutaneous infusion (infusion under the skin).

The recommended dose is 1080 mg twice weekly for adults.

For adolescents between 12 and 17 years, the dose is based on body weight.

Efficacy

The efficacy of Aspaveli in the treatment of C3G and IC-MPGN was investigated in the VALIANT pivotal study.

In this study, patients received either Aspaveli or a placebo (dummy drug) over 26 weeks.

A statistically significant reduction in proteinuria was demonstrated for treatment with Aspaveli: The mean decrease was 68 % versus placebo after 26 weeks. In addition 60.3 % of patients achieved a reduction in proteinuria of at least 50 %. An improvement in C3 deposits was also demonstrated in 74.3% of patients treated with Aspaveli. Renal function also remained stable, while it deteriorated in those on placebo.

Precautions, undesirable effects, & risks

Aspaveli may not be used in those who are hypersensitive to one of the active substances or any of the excipients.

Because it blocks complement activation, there is an increased risk of severe infection by encapsulated bacteria such as Streptococcus pneumoniae, Neisseria meningitidis, and Haemophilus influenzae.

The most common undesirable effects include injection site reactions, upper respiratory tract infections, diarrhoea, and headache.

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

C3G and IC-MPGN are rare, severe renal diseases for which there is no specifically authorised treatment. The studies submitted showed that Aspaveli can significantly improve key symptoms, in particular proteinuria, which is an important marker for disease progression.

It was also demonstrated that renal function remains stable with treatment, while this often deteriorates rapidly without effective therapy.

Taking all the risks and precautions into account, and based on the available data, the benefits of Aspaveli outweigh the risks. Swissmedic has therefore approved the indication extension for Aspaveli in Switzerland for the treatment of C3G and IC-MPGN in adults and adolescents aged 12 years and over.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Aspaveli®

Information for patients (package leaflet): Information for patients 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.

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