swissmedic

Summary report on authorisation dated 3 June 2025

Ultomiris® (active substance: ravulizumab)

Indication extension in Switzerland: 16 February 2023

Concentrate for solution for infusion for the treatment of adults with generalised myasthenia gravis (gMG) who are anti-acetylcholine receptor antibody positive, in addition to the standard therapy

About the medicinal product

The medicinal product Ultomiris contains the active substance ravulizumab.

Ultomiris is used in addition to the standard therapy for the treatment of adult patients with generalised myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive.

Myasthenia gravis is a chronic, neuromuscular autoimmune disease that leads to muscle weakness. The immune system's antibodies attack the body's own acetylcholine receptors, which are responsible for muscle contraction.

Ultomiris was approved by Swissmedic on 20 January 2020 for the treatment of adults with paroxysmal nocturnal haemoglobinuria (PNH). In addition, an indication extension for Ultomiris for the treatment of adults and children weighing at least 10 kg with atypical haemolytic uraemic syndrome (aHUS) was approved on 24 August 2021. On 14 July 2022, a further indication extension for Ultomiris for the treatment of children and adolescents weighing at least 10 kg with paroxysmal nocturnal haemoglobinuria (PNH) was approved by Swissmedic for use in Switzerland. A third indication extension for Ultomiris for the treatment of adults with NMOSD who are AQP4 antibody-positive was approved on 29 August 2023 .

Since myasthenia gravis is a rare and life-threatening disease, the present indication extension for Ultomiris 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 Ultomiris 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 Ultomiris in Switzerland, Swissmedic accepted the assessment and approval decision of the European Medicines Agency (EMA) (EMEA/H/C/004954/II/0026) 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 medicinal product.

www.ema.europa.eu

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Ultomiris®

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.