swissmedic

Public Summary SwissPAR dated 12.11.2021

Ultomiris® (active substance: ravulizumab)

Indication extension in Switzerland: 24 August 2021

Concentrate for solution for infusion, for the treatment of patients weighing at least 10 kg with atypical haemolytic uraemic syndrome (aHUS)

Information on authorisation

Ultomiris was approved by Swissmedic on 20 January 2020 for the treatment of adults with paroxysmal nocturnal haemoglobinuria (PNH). The indication extension means that adults and children weighing at least 10 kg who have atypical haemolytic uraemic syndrome (aHUS) can now also be treated with Ultomiris. Ultomiris may only be used for treatment of aHUS in patients who have not previously been treated with complement inhibitors (inhibitors of the complement system, part of the immune system) or who have received a medicine containing the active substance eculizumab with a positive effect for at least three months.

Atypical haemolytic uraemic syndrome (aHUS) is a very rare disease in which the complement system is uncontrollably and excessively activated due to a lack of, or the incorrect function of, key proteins for the cellular signalling process. Patients with aHUS develop blood clots throughout the body, blocking small vessels (capillaries) in particular. This impairs the blood supply to vital organs and can irreversibly damage them.

As paroxysmal nocturnal haemoglobinuria (PNH) and atypical haemolytic uraemic syndrome (aHUS) are very rare diseases, Ultomiris has been authorised as an "orphan drug". "Orphan drug" is a designation given to important medicinal products for rare diseases.

Ultomiris was authorised 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 the foreign regulatory agency, 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 of the European Medicines Agency (EMA) and the EMA's authorisation decision, and has not conducted its own scientific review.

Accordingly, in the SwissPAR (Swiss Public Assessment Report) and the resulting Public

Summary SwissPAR, Swissmedic refers to the Assessment Report and the short report issued by the reference authority: (www.ema.europa.eu)

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Ultomiris®

Healthcare professionals (doctors, pharmacists and others) 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 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.