swissmedic

Public Summary SwissPAR dated 19 March 2020

Ultomiris® (active substance: ravulizumab)

First authorisation in Switzerland: 20.01.2020

Concentrate for solution for infusion for the treatment of adult patients with paroxysmal nocturnal haemoglobinuria (PNH).

Information on authorisation

Since paroxysmal nocturnal haemoglobinuria (PNH) is a rare disease, Ultomiris has been authorised as an “orphan drug”. The term "orphan drug" refers to important medicines for rare diseases that meet specific requirements. Medicinal products of this kind benefit from simplified authorisation conditions in Switzerland.

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 public overview issued by the reference authority: In connection with the Public Summary SwissPAR for Ultomiris, we refer to the public summary issued by the EMA:
EMA: Overview of Ultomiris and why it is authorised in the EU
(www.ema.europa.eu)

Further information on the medicinal product

Information for medical professionals: Information for healthcare professionals for Ultomiris®

Healthcare professionals (doctors, pharmacists and others) can answer any further questions.

This information is correct as at the date above. 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.