swissmedic

Public Summary SwissPAR dated 19.02.2020

Cablivi® (active substance: Caplacizumab)

First authorisation in Switzerland: 01.10.2019: 01.10.2019

Medicinal product (powder and solvent for solution for injection) for the treatment of adults who have an episode of acquired thrombotic thrombocytopenic purpura (aTTP).

Information on authorisation

Since acquired thrombotic thrombocytopenic purpura (aTTP) is a rare disease, Cablivi 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.

Cablivi 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.

Swissmedic accepted the assessment of the European Medicines Agency (EMA) and the EMA’s authorisation decision when making its own decision on whether to authorise Cablivi in Switzerland.

If Swissmedic does not carry out its own scientific assessment, Swissmedic refers to the Assessment Report of the reference authority in both the SwissPAR (Swiss Public Assessment Report) and the resulting Public Summary SwissPAR. Since no separate review, and therefore no separate SwissPAR exists, in the Public Summary SwissPAR for Cablivi we refer to the public short report issued by the EMA: EMA: An overview of Cablivi and why it is authorised in the EU (www.ema.europa.eu)

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Cablivi®

Information for patients (package leaflet): Patient information Cablivi®

If you have any further questions, please address them to healthcare professionals (doctor, pharmacist, etc.).

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.