swissmedic

Public Summary SwissPAR dated 19.10.2021

Cablivi® (active substance: caplacizumab)

Indication extension in Switzerland: 1 July 2021

Medicinal product (powder and solvent for solution for injection) for the treatment of adults and adolescents aged 12 years and over who have an episode of acquired thrombotic thrombocytopenic purpura (aTTP).

Information on authorisation

Cablivi was authorised by Swissmedic on 1 October 2019 for the treatment of adults who have an episode of acquired thrombotic thrombocytopenic purpura (aTTP)[1]. This indication extension means that adolescents aged 12 years and over weighing at least 40 kg can now also be treated.

Since this blood disorder is a rare disease, the medicine 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.

In deciding whether to authorise Cablivi 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)

[1] Thrombotic thrombocytopenic purpura (TTP) is a rare, life-threatening blood disorder with two recognised types: acquired (aTTP) and congenital (cTTP). In TTP, blood clots form, blocking the small blood vessels of the brain and kidneys in particular, which leads to serious organ damage.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Cablivi®

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

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.