swissmedic

Public Summary SwissPAR dated 21 May 2024

Uplizna® (active substance: inebilizumab)

Authorisation in Switzerland: 4 March 2024

Concentrate for solution for infusion for the treatment of adults with NMOSD who are AQP4 antibody-positive

Information on authorisation

The medicinal product Uplizna contains the active substance inebilizumab.

Uplizna is used to treat adults with neuromyelitis optica spectrum disorder (NMOSD) who have antibodies against the protein AQP4 (Aquaporin-4).

NMOSD is a rare autoimmune disease of the central nervous system mainly affecting the optic nerves and the bone marrow. Preventing disease flare-ups is an important objective in the treatment of NMOSD.

Since NMOSD is a rare and life-threatening disease, the medicinal product Uplizna has been authorised as an orphan drug. The term "orphan drug" is used to refer to important medicines for rare diseases.

Uplizna 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 Uplizna in Switzerland, Swissmedic accepted the assessment and approval decision of the European Medicines Agency (EMA; reference number EMA/266309/2022) and has only conducted a limited scientific review.
Accordingly, in the SwissPAR (Swiss Public Assessment Report) and the resulting Public Summary SwissPAR, Swissmedic refers to the publicly available Assessment Report issued by the reference authority: www.ema.europa.eu.

Further information on the medicinal product

At the time of publication of the Public Summary SwissPAR for Uplizna, the Information for healthcare professionals was not yet available. As soon as the medicinal product becomes available in Switzerland, the Information for healthcare professionals will be made available on the following website: www.swissmedicinfo.ch

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 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.