swissmedic

Public Summary SwissPAR dated 19.03.2021

Ondexxya® (active substance: andexanet alfa)

Temporary authorisation in Switzerland: 2 December 2020

Medicinal product for the treatment of adults with life-threatening haemorrhage who have been treated with the anticoagulants apixaban or rivaroxaban

About the medicinal product

The medicinal product Ondexxya contains the active substance andexanet alfa.

The anticoagulants apixaban or rivaroxaban can be used for patients with an increased risk of thrombosis (blood clots). In the event of uncontrollable bleeding, Ondexxya reverses the effect of these anticoagulants. This restores the patient's natural blood clotting ability and the bleeding can be stopped.

Ondexxya is administered as a solution for infusion through the veins. The treatment is carried out exclusively in hospitals with medical monitoring.

Information on authorisation

In deciding whether to authorise the medicinal product Ondexxya, Swissmedic took into account the assessments of the European Medicines Agency (EMA), the US Food and Drug Administration (FDA) and the corresponding product information.

The medicinal product Ondexxya was temporarily authorised in Switzerland (Art. 9a TPA), as not all clinical trials had been completed at the time of authorisation.
The temporary authorisation is contingent on the timely submission of the data requested by Swissmedic. Once these authorisation conditions have been met, the temporary authorisation can be converted into an ordinary authorisation.

Since the assessment of the clinical data was based on the assessment reports of the foreign partner authorities, the preconditions for a SwissPAR (Swiss Public Assessment Report) and a resulting Public Summary SwissPAR are not fully met. Swissmedic refers to the authorisation of the foreign comparator products.
www.ema.europa.eu
www.fda.gov

Further information on the medicinal product

Information for healthcare professionals:
Information for healthcare professionals Ondexxya®

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.