swissmedic

Public Summary SwissPAR dated 8 July 2024

Amvuttra® (active substance: vutrisiran)

Authorisation in Switzerland: 23 June 2023

Solution for injection in a pre-filled syringe for the treatment of hereditary transthyretin amyloidosis (hATTR amyloidosis) in adults with stage 1 or 2 polyneuropathy

Information on authorisation

The medicinal product Amvuttra contains the active substance vutrisiran.

Amvuttra is used for the treatment of a disease called "hereditary ATTR" or "hATTR amyloidosis". This is a hereditary disease.

In people with this disease, small fibres of TTR protein clump together and form deposits called "amyloid". Amyloid can accumulate on or in the nerves, heart, or other parts of the body, where they interfere with their normal functions.

Amvuttra works by reducing the amount of TTR protein produced by the liver, meaning that the blood contains less TTR protein that can form amyloid. This can help to alleviate the effects of this disease.

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

Amvuttra 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 Amvuttra in Switzerland, Swissmedic accepted the assessment and approval decision of the European Medicines Agency (EMA; reference number EMA/CHMP/689555/2022) 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

Information for healthcare professionals: Information for healthcare professionals Amvuttra®

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

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.