swissmedic

Summary report on authorisation dated 19 January 2026

Amvuttra® (active substance: vutrisiran)

Indication extension in Switzerland: 16 October 2025

Solution for injection in a pre-filled syringe for the treatment of wild-type or hereditary transthyretin amyloidosis in adults with cardiomyopathy (ATTR-CM)

About the medicinal product

The medicinal product Amvuttra contains the active substance vutrisiran.

Amvuttra is used to treat a disease called "wild-type or hereditary transthyretin amyloidosis" in adults with cardiomyopathy (ATTR-CM). This is a disease that is either inherited (hereditary) or that occurs without a genetic cause, generally at an advanced age.

In people with this disease, TTR protein clumps together and forms deposits called "amyloid". Amyloid can accumulate in the nerves, heart, or other parts of the body and interfere with normal functioning. Amyloid that is deposited in the heart muscle stiffens the wall of the heart, reducing its ability to fill with blood and pump it onwards effectively. This can result in symptoms such as dyspnoea on exertion, fatigue, swelling or abnormal heart rhythms.

Amvuttra works by reducing the amount of TTR protein released from the liver into the blood. As a result, less amyloid is formed. This can help to alleviate the effects of this disease.

Since transthyretin 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.

Swissmedic has authorised this indication extension for Amvuttra under Article 13 of the Therapeutic Products Act (TPA). This means that the indication extension 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 this indication extension for Amvuttra in Switzerland, Swissmedic accepted the assessment and approval decision of the European Medicines

Agency (EMA; Reference Number EMA/CHMP/177587/2025// Procedure Number EMEA/H/C/00582/II/0015) 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 Summary report on authorisation.

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.