swissmedic

Summary report on authorisation dated 16 March 2026

BEYONTTRA® (active substance: acoramidis as acoramidis hydrochloride)

Authorisation in Switzerland: 18 December 2025

Film-coated tablets for the treatment of wild-type or hereditary transthyretin amyloidosis in adult patients with cardiomyopathy (ATTR-CM)

About the medicinal product

The medicinal product BEYONTTRA contains the active substance acoramidis as acoramidis hydrochloride.

BEYONTTRA is used for the treatment of adults with cardiomyopathy (a disease affecting the heart muscle) who have developed transthyretin amyloidosis as a consequence (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, the transthyretin protein breaks apart into single units, which form fibrous clumps that deposit in the heart. These deposits are known as “amyloid”. Amyloid deposited in the heart muscle causes the heart wall to stiffen, meaning it can no longer pump consistently. As a result, the body is no longer sufficiently supplied with blood. This can lead to symptoms such as dyspnoea on exertion, fatigue, swelling, or abnormal heart rhythms.

BEYONTTRA acts by stabilising the transthyretin protein, thereby slowing the development of amyloid deposits in the heart.

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

BEYONTTRA was 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 BEYONTTRA in Switzerland, Swissmedic accepted the assessment and approval decision of the European Medicines Agency (EMA; procedure number EMEA/H/C/006333/0000) and has not conducted its own scientific review.

Accordingly, in the SwissPAR (Swiss Public Assessment Report) and the resulting Summary report on authorisation, Swissmedic refers to the Assessment Report and summary report issued by the reference authority: www.ema.europa.eu.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals BEYONTTRA®

Information for patients (package leaflet): Information for patients BEYONTTRA®
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.