swissmedic

Public Summary SwissPAR dated 5 April 2023

VAZKEPA® (active substance: icosapent ethyl)

First authorisation in Switzerland: 22 November 2022

Medicinal product (oral capsule) for the prevention of cardiovascular events in adults

Information on authorisation

The medicinal product Vazkepa contains the active substance icosapent ethyl. This is a highly purified Omega-3 fatty acid from fish oil.

Vazkepa is used in adults with heart disease or diabetes (and are therefore at increased risk of cardiovascular events) and who have high levels of triglycerides (a type of fat) in their blood. These patients are already being treated with a statin, which reduces blood cholesterol. Vazkepa reduces levels of triglycerides and lowers the risk of cardiovascular events such as heart attack, stroke or death due to cardiovascular disease.

In deciding whether to authorise the medicinal product Vazkepa, containing the active substance icosapent ethyl, Swissmedic took into account the assessment of the European Medicines Agency (EMA) as well as the corresponding product information.

Since the assessment of the clinical data was based on the assessment reports of the foreign authority, 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 reference authority.

www.ema.europa.eu

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals VAZKEPA®

Information for patients:

Information for patients VAZKEPA®

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.