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Public Summary SwissPAR dated 11 November 2022

Kapruvia® (active substance: difelikefalin)

First authorisation in Switzerland: 16 August 2022

Medicinal product (solution for injection) for the treatment of moderate to severe itching associated with chronic kidney disease in adult patients on haemodialysis.

Information on authorisation

The medicinal product Kapruvia contains the active substance difelikefalin. It is used for the treatment of moderate to severe itching associated with chronic kidney disease in adult patients on haemodialysis. Haemodialysis is a procedure used in patients with kidney failure to clean the blood (blood washing).

Kapruvia was authorised as part of the joint initiative of the Access Consortium. This joint initiative is a collaborative project between the drug regulatory authorities in Australia (Therapeutic Goods Administration, TGA), Canada (Health Canada, HC), Singapore (Health Sciences Authority, HSA), the United Kingdom (Medicines & Healthcare products Regulatory Agency, MHRA), Swissmedic and the pharmaceutical industry. The joint initiative coordinates the assessment of authorisation applications for new active substances that have been submitted in at least two of the five countries.

The authorisation application for Kapruvia was submitted for assessment to the regulatory authorities in Singapore, Australia, Canada and Switzerland. Each country assessed a part of the application and then shared and discussed the results. At the end of the process, each authority decided on the application independently.

Swissmedic considered the assessments by the foreign reference authorities in its decision on the authorisation. Accordingly, and since Swissmedic has not produced a complete SwissPAR (Swiss Public Assessment Report), it cannot issue a complete Public Summary SwissPAR. Swissmedic therefore refers to the relevant publications issued by the authorities involved.

Further details of the Access joint initiative are published on the Swissmedic website. Access Consortium (swissmedic.ch).

Further information on the medicinal product

At the time of publication of the Public Summary SwissPAR for Kapruvia, the Information for healthcare professionals was not yet available. As soon as the medicine becomes available in Switzerland, the Information for healthcare professionals will be

made available on the following website: www.swissmedicinfo.ch

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 in 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.