

Summary report on authorisation dated 3 July 2026

## Ezmekly<sup>®</sup> (active substance: mirdametinib)

Temporary authorisation in Switzerland: 9 April 2026

Hard capsules or tablets for suspension for oral administration for the treatment of plexiform neurofibromas in adults and children aged 2 years and above with neurofibromatosis type 1

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### About the medicinal product

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Ezmekly contains the active substance mirdametinib.

Ezmekly is used to treat plexiform neurofibromas – benign (non-cancerous) tumours that grow along nerves – in adults, adolescents and children aged 2 and above with the genetic condition neurofibromatosis type 1 (NF1). NF1 is a rare hereditary condition that can cause tumours to form along nerves. Ezmekly works by blocking certain proteins that are involved in tumour cell growth, thereby helping to shrink the tumours.

The medicinal product Ezmekly has been authorised in Switzerland on a temporary basis (in accordance with Art. 9a of the Therapeutic Products Act) since not all clinical trials data were available at the time of authorisation.

The temporary authorisation is contingent on the outstanding clinical data requested by Swissmedic being submitted on schedule. The data in question are from clinical trials that are still ongoing or have yet to be concluded. Once these authorisation conditions have been met, the temporary authorisation can be converted into an ordinary authorisation if the outcome of the benefit-risk assessment of the results is positive.

Ezmekly was authorised under Article 13 of the Therapeutic Products Act (TPA). This authorisation procedure is applied in certain circumstances when a medicinal product is already authorised in another country with comparable medicinal product control.

In such cases, Swissmedic may take account of the results of the assessments conducted by that country's medicinal products regulatory authority. 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 Ezmekly in Switzerland, Swissmedic accepted the assessment and approval decision of the European Medicines Agency (EMA). Swissmedic has not, therefore, 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](http://www.ema.europa.eu)

Since this is a rare and life-threatening or chronically debilitating disease, the medicinal product Ezmekly has been authorised as an orphan drug. The term “orphan drug” refers to medicinal products used to treat patients with rare diseases.

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## Further information on the medicinal product

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Information for healthcare professionals: [Information for healthcare professionals Ezmekly®](#)

Information for patients (package leaflet): [Information for patients Ezmekly®](#)

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.