swissmedic

Summary report on authorisation dated 15 September 2026

Tranylcypromine Rivopharm® (active substance: tranylcypromine

Authorisation in Switzerland: 12 May 2026

Film-coated tablets for the treatment of depressive episodes (major depression) in adults

About the medicinal product

Tranylcypromine Rivopharm contains the active ingredient tranylcypromine and is used to treat depressive episodes (episodes of major depression) in adults.

Tranylcypromine Rivopharm is used as a reserve treatment. That means it is used when at least two standard antidepressants have not been sufficiently effective or cannot be used for medical reasons (e.g. the patient did not tolerate them).

Tranylcypromine Rivopharm was authorised under Article 14 paragraph 1 letter a^{bis} of the Therapeutic Products Act (TPA). The Therapeutic Products Act permits the authorisation of certain categories of medicines under a simplified procedure, provided this is compatible with the quality, safety, and efficacy requirements, and there is no conflict with Swiss interests or international obligations.

The authorisation of Tranylcypromine Rivopharm is based on the medicinal product Jatrosom (film-coated tablets), which contains the same active substance and has been authorised in a comparable indication and dosage in Germany for more than 10 years.

Swissmedic assessed the quality data on the active substance and finished product, but did not conduct its own comprehensive scientific review of other aspects. Efficacy and safety were only reviewed in summarised form.

The requirements for issuing a comprehensive SwissPAR (Swiss Public Assessment Report) and the resulting Summary report on authorisation have therefore not been met. Swissmedic refers to the authorisation of the foreign comparator medicinal product:

https://www.ema.europa.eu

Further information on simplified authorisation according to Art. 14 para. 1 let. a^{bis} TPA can be found in the Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA).

Further information on the medicinal product

At the time of publication of the Summary report on authorisation for Tranylcypromine Rivopharm, the Information for healthcare professionals and the Patient information were not yet available. As soon as the medicinal product becomes available in Switzerland, the product information 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 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.