swissmedic

Summary report on authorisation dated 4 April 2025

# Desveneurax® (active substance: desvenlafaxine)

## Authorisation in Switzerland: 22 November 2024

## Prolonged-release tablets for the treatment of severe depressive episodes in adults

## Information on authorisation

Desveneurax contains the active substance desvenlafaxine.

It is used to treat adults with severe depressive episodes, also known as major depressive disorder (MDD).

Desveneurax was authorised under Art. 14 para. 1 let. a$^{bis}$ of the Therapeutic Products Act (TPA). The TPA enables certain categories of medicines to be authorised according to 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 Desveneurax is based on the medicinal product Pristiq, which contains the same active substance and has been authorised for a comparable indication, dosage, and use in Spain for more than 10 years.

Swissmedic assessed the quality data on the active substance and finished medicinal product but did not conduct its own comprehensive scientific review for 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.

Further information on simplified authorisation according to Art. 14 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 Desveneurax, the Information for healthcare professionals was not yet available. As soon as the medicinal product 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 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.