swissmedic

Summary report on authorisation dated 25 October 2024

Levocalm® (active substance: levodropizine)

First authorisation in Switzerland: 18 July 2024

Syrup for the symptomatic treatment of non-productive cough in adults, adolescents and children from the age of 2 years

Information on authorisation

The medicinal product Levocalm contains the active substance levodropizine.

Levocalm has been authorised for the symptomatic treatment[1] of non-productive cough (cough without expectoration) in adults, adolescents and children from the age of 2 years. The maximum treatment duration without medical advice is 7 days.

Levocalm 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 Levocalm is based on the foreign reference medicinal product Levotuss 30 mg/5 mL syrup, which contains the same active substance and has been authorised for a comparable indication, dosage, and use in Italy 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 (Levodropropizine ELC 30 mg/5 mL syrup), which is authorised in Malta and from which the product information was adopted.

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)

[1] Symptomatic treatment: Treatment of the disease symptoms only without eliminating the underlying cause of the disease.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Levocalm®

Information for patients (package leaflet): Information for patients Levocalm®

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.