swissmedic

Public Summary SwissPAR dated 28 April 2023

Spaverin® (active substance: drotaverine hydrochloride)

First authorisation in Switzerland: 30 January 2023

Medicinal product (tablet) for the treatment of gastrointestinal complaints in adults

Information on authorisation

The medicinal product Spaverin contains the active substance drotaverine hydrochloride.

Spaverin is used for the symptomatic treatment of gastrointestinal complaints (pain, cramps) in the context of functional disorders of the gastrointestinal tract in adults.

Spaverin 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 Spaverin is based on the authorisation of the reference authority in Hungary. The active substance drotaverine hydrochloride has been authorised for a comparable indication, dosage and use in Hungary 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 SwissPAR (Swiss Public Assessment Report) and the resulting Public Summary SwissPAR 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 Public Summary SwissPAR for Spaverin, the Information for healthcare professionals and the Patient information (package leaflet) were not yet available. As soon as the medicine becomes available in Switzerland, the Information for healthcare professionals and the Patient 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 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.