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Public Summary SwissPAR dated 28.01.2021

Mictonorm® (active substance: propiverine hydrochloride)

First authorisation in Switzerland: 13.08.2020

Medicinal product (modified-release capsule) for the treatment of adult patients with urinary incontinence or an overactive bladder

Information on authorisation

The medicinal product Mictonorm, containing the active substance propiverine hydrochloride, is a modified-release capsule medicine. This type of capsule allows the medication to be released slowly over a long period.

It has been authorised for the treatment of urinary incontinence or the increased need or sudden urge to urinate, as seen in adult patients with overactive bladder.
Urinary incontinence means a person loses control of their bladder and unintentionally passes urine. An overactive bladder is a group of symptoms that include a sudden urge to urinate, which sometimes results in leaking during the day or night.

Mictonorm 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.

At the time the application was submitted, Mictonorm, containing the active substance propiverine hydrochloride, had demonstrably been used in a medicinal product that had been authorised for at least 10 years in at least one EU or EFTA country, and that is comparable in terms of indications, dosage and method of administration. The preconditions for simplified authorisation were therefore met.

Consequently, Swissmedic is not conducting its own comprehensive scientific review, and the preconditions for a SwissPAR (Swiss Public Assessment Report) and a resulting Public Summary SwissPAR do not apply. Swissmedic refers to the authorisation of the foreign comparator medicinal product:

The marketing authorisation for Mictonorm is based on the drug Mictonorm XL 30 mg, which contains the same active ingredient and has been authorised in the United Kingdom for more than 10 years.

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

Information for healthcare professionals:
Information for healthcare professionals Mictonorm®

Information for patients (package leaflet):
Patient information Mictonorm®

If you have any further questions, please address them to healthcare professionals (doctor, pharmacist, etc.).

This information is correct as at the date above. 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.