

Public Summary SwissPAR dated 11 November 2022

## Softigyn<sup>®</sup> (active substance: live *Lactobacillus plantarum* P17630)

First authorisation in Switzerland: 26 July 2022

Medicinal product (vaginal capsule) to restore and maintain the physiological vaginal flora in adult women.

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### Information on authorisation

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The medicinal product Softigyn contains the active substance *Lactobacillus plantarum*. It is a vaginal capsule containing 100 million units of the bacterium, which normally colonises the vagina of healthy women. It prevents the development of other bacteria that can cause diseases.

Softigyn is used to restore and maintain the natural vaginal flora, for example:

- if there are signs of vaginal inflammation (vaginitis), such as itching, burning or vaginal discharge
- during or after local or systemic treatment<sup>1</sup> with anti-infectives<sup>2</sup>
- to prevent recurrent vaginal mycosis.

Softigyn is not a substitute for treatment with antibiotic or antimycotic medicinal products<sup>3</sup>.

Softigyn was authorised under Art. 14 para. 1 let. a<sup>bis</sup> 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 Softigyn is based on the medicinal product Ecocillin, 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.

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<sup>1</sup> Local/systemic treatment: Local treatment means the use of medicinal products in the specific area where they should have their therapeutic effect. In contrast, a medicinal product or therapy used for systemic treatment affects the entire body.

<sup>2</sup>Anti-infectives: Medicinal products used for the treatment of infectious diseases. They act against bacteria, viruses, fungi and parasites.

<sup>3</sup> Antimycotic medicinal product: Medicinal product for the treatment of fungal infections

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:

<https://www.ema.europa.eu>

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).

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## Further information on the medicinal product

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Information for healthcare professionals: [Information or healthcare professionals Softigyn®](#)

Information for patients (package leaflet): [Information for patients Softigyn®](#)

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 in 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.