25 March 2021
EMA/CHMP/156178/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Lydisilka

estetrol / drospirenone

On 25 March 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Lydisilka, intended for oral contraception. The applicant for this medicinal product is Estetra SPRL.

Lydisilka will be available as 14.2 mg / 3 mg film-coated tablets. The active substances of Lydisilka are estetrol (an oestrogen) drospirenone (a progestogen) (ATC code: G03AA18). Estetrol is a new chemically synthesised oestrogen, which in humans is produced only by the liver of the human foetus during pregnancy and reaches the maternal circulation through the placenta. Estetrol suppresses follicle stimulating hormone activity and stabilises the bleeding pattern. Drospirenone is a previously known progestogen, which suppresses luteinizing hormone activity. These actions result in a contraceptive effect which is based on the interaction of various factors, the most important of which is inhibition of ovulation.

The benefit of Lydisilka is its ability to provide oral contraception. The most common side effects are metrorrhagia, headache, acne, vaginal haemorrhage and dysmenorrhoea.

The full indication is:

> Oral contraception. The decision to prescribe Lydisilka should take into consideration the individual woman's current risk factors, particularly those for venous thromboembolism (VTE), and how the risk of VTE with Lydisilka compares with other combined hormonal contraceptives (CHCs).

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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