9 November 2017
EMA/CHMP/724429/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Intrarosa

prasterone

On 9 November 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Intrarosa, intended for the treatment of vulvar and vaginal atrophy in postmenopausal women. The applicant for this medicinal product is Endoceutics Ltd.

Intrarosa will be available as a 6.5 mg pessary. The active substance of Intrarosa is prasterone, also known as dehydroepiandrosterone (DHEA), a precursor steroid which is converted into oestrogens and androgens. The medicine increases the number of superficial and intermediate cells and decreases the number of parabasal cells in the vaginal mucosa via an oestrogen-mediated mechanism. In addition, it decreases the vaginal pH towards the normal range, thus facilitating the growth of the normal bacterial flora.

The benefit with Intrarosa is its ability to improve dyspareunia. The most common side effect is vaginal discharge.

The full indication is: "Intrarosa is indicated for the treatment of vulvar and vaginal atrophy in postmenopausal women having moderate to severe symptoms".

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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact