



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 July 2020
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Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion

Dapivirine Vaginal Ring 25 mg dapivirine

On 23 July 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion in accordance with Article 58 of Regulation (EC) No 726/2004¹ for the medicinal product Dapivirine Vaginal Ring 25 mg, intended for prophylaxis against HIV-1 infection via vaginal intercourse in HIV-uninfected women 18 years and older in combination with safer sex practices when oral pre-exposure prophylaxis (PrEP) is not/cannot be used or is not available. This medicinal product has been developed by International Partnership for Microbicides Belgium AISBL.

Dapivirine Vaginal Ring 25 mg will be available as a vaginal delivery system (25 mg). The active substance of Dapivirine Vaginal Ring 25 mg is dapivirine, a non-nucleoside inhibitor of HIV-1 reverse transcriptase (NNRTI), which blocks the activity of the viral enzyme HIV-1 reverse transcriptase (RT) thereby preventing viral replication.

The benefits with Dapivirine Vaginal Ring 25 mg are its ability to achieve a reduction in the development of HIV-1 antibodies (i.e. seroconversion), which is a measure for the presence of HIV in the body. The most common side effects are urinary tract infection, vaginal discharge, vulvovaginal pruritus, vulvovaginitis, pelvic and lower abdominal pain.

The full indication is:

“Reducing the risk of HIV-1 infection via vaginal intercourse in HIV-uninfected women 18 years and older in combination with safer sex practices when oral PrEP is not/cannot be used or is not available”.

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).

Dapivirine Vaginal Ring 25 mg is intended exclusively for markets outside the European Union.

¹ Scientific opinion in accordance with Article 58 of (EC) No Regulation 726/2004 in the context of cooperation with the World Health Organisation (WHO)

