



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 June 2025
EMA/CHMP/199904/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion (post authorisation)

Dapivirine Vaginal Ring 25 mg dapivirine

On 19 June 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion in accordance with Article 58 of Regulation (EC) No 726/2004¹, recommending a change to the product information for the medicinal product Dapivirine Vaginal Ring 25 mg. The change for this medicinal product has been requested by International Partnership for Microbicides Belgium AISBL.

The CHMP adopted an extension to the existing indication to allow the use of Dapivirine Vaginal Ring 25 mg in women from 16 years of age. The full indications for Dapivirine Vaginal Ring 25 mg will therefore be as follows:²

Reducing the risk of HIV-1 infection via vaginal intercourse in HIV-uninfected women **16**
~~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 updated summary of product characteristics (SmPC), which will be published on the EMA website.

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)

² New text in bold, removed text as strikethrough

