EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 December 2017
EMA/CHMP/804062/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Truvada

emtricitabine / tenofovir disoproxil

On 14 December 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Truvada. The marketing authorisation holder for this medicinal product is Gilead Sciences International Limited.

The CHMP adopted an extension to an existing indication as follows[2]:

> "*Treatment of HIV-1 infection:*
>
> Truvada is indicated in antiretroviral combination therapy for the treatment of HIV-1 infected adults (see section 5.1).
>
> Truvada is also indicated for the treatment of HIV-1 infected adolescents, with NRTI resistance or toxicities precluding the use of first line agents~~, aged 12 to < 18 years~~ (see section**s 4.2, 4.4 and 5.1**).
>
> *Pre-exposure prophylaxis (PrEP):*
>
> Truvada is indicated in combination with safer sex practices for pre-exposure prophylaxis to reduce the risk of sexually acquired HIV-1 infection in adults **and adolescents** at high risk (see sections **4.2**, 4.4 and 5.1)."

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to 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
[2] New text in bold, removed text as strikethrough

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