21 July 2016
EMA/CHMP/488317/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Truvada

emtricitabine / tenofovir disoproxil

On 21 July 2016, 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 Ltd.

The CHMP adopted a new indication as follows:

> "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 at high risk (see sections 4.4 and 5.1)."

For information, the full indications for Truvada will be 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).
>
> **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 at high risk (see sections 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

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