20 September 2018
EMA/CHMP/619909/2018
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (initial authorisation)**

# Delstrigo

## doravirine / lamivudine / tenofovir disoproxil

On 20 September 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Delstrigo, intended for the treatment of HIV-1 infection. The applicant for this medicinal product is Merck Sharp & Dohme B.V.

Delstrigo is a fixed dose combination of three active substances, doravirine, lamivudine and tenofovir disoproxil, and will be available as 100 mg / 300 mg / 245 mg film-coated tablets (ATC code: J05AR). Doravirine is a new non-nucleoside reverse transcriptase inhibitor (NNRTI). Lamivudine and tenofovir disoproxil are substrates and competitive inhibitors of HIV reverse transcriptase. After phosphorylation, they are incorporated into the viral DNA chain, resulting in chain termination.

The benefits with Delstrigo are its ability to achieve a potent antiretroviral response in a once daily, single pill regimen. The most common side effects are nausea and headache.

The full indication is: “Delstrigo is indicated for the treatment of adults infected with HIV-1 without past or present evidence of resistance to the NNRTI class, lamivudine, or tenofovir (see sections 4.4 and 5.1)."

It is proposed that Delstrigo be prescribed by physicians experienced in the management of HIV infection.

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