20 July 2017
EMA/411074/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Symtuza

darunavir / cobicistat / emtricitabine / tenofovir alafenamide

On 20 July 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Symtuza, intended for the treatment of HIV infection. The applicant for this medicinal product is Janssen-Cilag International N.V.

Symtuza is a fixed-dose combination of four active substances (darunavir, cobicistat, emtricitabine and tenofovir alafenamide), and will be available as 800 mg/150 mg/200 mg/10 mg film-coated tablets (ATC code: not yet assigned). Darunavir inhibits the HIV protease and prevents the formation of mature infectious virus particles. Emtricitabine and tenofovir alafenamide are substrates and competitive inhibitors of HIV reverse transcriptase. After phosphorylation, they are incorporated into the viral DNA chain, resulting in chain termination. Cobicistat enhances the systemic exposure of darunavir and has no direct antiviral effect.

The benefits with Symtuza are its ability to achieve effective antiretroviral response in a once daily, single pill regimen. The most common side effects are diarrhoea, nausea, fatigue and rash.

The full indication is:

“Symtuza is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and adolescents (aged 12 years and older with body weight at least 40 kg).

Genotypic testing should guide the use of Symtuza (see sections 4.2 and 5.1).”

It is proposed that Symtuza 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

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