19 November 2015
EMA/CHMP/772058/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Lopinavir/Ritonavir Mylan

lopinavir / ritonavir

On 19 November 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Lopinavir/Ritonavir Mylan, intended for the treatment of HIV infection in adults, adolescents and children above the age of 2 years. The applicant for this medicinal product is MYLAN S.A.S.

Lopinavir/Ritonavir Mylan will be available as film-coated tablets (100 mg/25 mg and 200 mg/50 mg). The active substances of Lopinavir/Ritonavir Mylan are lopinavir and ritonavir, antivirals for systemic use for the treatment of HIV infections (ATC code: J05AR10). Lopinavir is an inhibitor of the viral protease enzyme which is key for viral replication. Ritonavir slows down the rate at which lopinavir is metabolised by the liver.

Lopinavir/Ritonavir Mylan is a generic of Kaletra, which has been authorised in the EU since 20 March 2001. Studies have demonstrated the satisfactory quality of Lopinavir/Ritonavir Mylan, and its bioequivalence to the reference product Kaletra. A question and answer document on generic medicines can be found here.

The full indication is: "Lopinavir/ritonavir is indicated in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infected adults, adolescents and children above the age of 2 years. The choice of lopinavir/ritonavir to treat protease inhibitor experienced HIV-1 infected patients should be based on individual viral resistance testing and treatment history of patients". It is proposed that Lopinavir/Ritonavir Mylan be prescribed by physicians experienced in the treatment 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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