14 September 2017
EMA/CHMP/541227/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ritonavir Mylan

ritonavir

On 14 September 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 Ritonavir Mylan, intended for the treatment of HIV infection. The applicant for this medicinal product is Mylan S.A.S.

Ritonavir Mylan will be available as 100 mg film-coated tablets. The active substance of Ritonavir Mylan is ritonavir, an antiviral for systemic use (ATC code: J05AE03). Ritonavir is an inhibitor of the viral protease enzyme, which is key for viral replication; however, in small doses it is used in combination with other protease inhibitors to slow down the rate at which the latter are metabolised by the liver.

Ritonavir Mylan is a generic of Norvir, which has been authorised in the EU since 26 August 1996. Studies have demonstrated the satisfactory quality of Ritonavir Mylan, and its bioequivalence to the reference product Norvir. A question and answer document on generic medicines can be found here.

The full indication is: "Ritonavir is indicated in combination with other antiretroviral agents for the treatment of HIV 1 infected patients (adults and children of 2 years of age and older)". It is proposed that Ritonavir Mylan 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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