18 May 2017
EMA/301751/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Isentress

raltegravir

On 18 May 2017, 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 Isentress. The marketing authorisation holder for this medicinal product is Merck Sharp & Dohme Limited.

The CHMP recommended the approval of a new strength: Isentress 600 mg film-coated tablets, which will allow for a once-a-day regimen consisting of two tablets. The currently authorised formulations are taken twice a day.

The indication of Isentress 600 mg film-coated tablet will be as follows:

“Isentress 600 mg film coated tablets is indicated in combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV 1) infection in adults, and paediatric patients weighing at least 40 kg (see sections 4.2, 4.4, 5.1 and 5.2).”

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

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