



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

22 February 2018  
EMA/CHMP/87645/2018  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (post authorisation)

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### ISENTRESS raltegravir

On 22 February 2018, 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 adopted an extension to the existing indication to cover treatment of neonates. The new indication will be as follows<sup>2</sup>:

"ISENTRESS is indicated in combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection ~~in adults, adolescents, children, toddlers and infants from the age of 4 weeks~~ (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.

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

<sup>2</sup> Removed text as strikethrough

