

15 November 2012
EMA/CHMP/723089/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Intelence etravirine

On 15 November 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a variation to the terms of the marketing authorisation for the medicinal product Intelence. The marketing authorisation holder for this medicinal product is Janssen-Cilag International N.V. They may request a re-examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The extension adopted by the CHMP is to add a new strength (25 mg) to the existing product range.

The CHMP also adopted a new indication as follows:

“INTELENCE, in combination with a boosted protease inhibitor and other antiretroviral medicinal products, is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-experienced paediatric patients from 6 years of age.

The indication in paediatric patients is based on 48-week analyses of a single-arm, Phase II trial in antiretroviral treatment-experienced paediatric patients.”

For information, the full indications for Intelence will be as follows²:

“INTELENCE, in combination with a boosted protease inhibitor and other antiretroviral medicinal products, is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-experienced adult patients **and in antiretroviral treatment-experienced paediatric patients from 6 years of age** (see sections 4.4, 4.5 and 5.1).

The indication **in adults** is based on week 48 analyses from 2 Phase III trials in highly pre-treated patients where INTELENCE was investigated in combination with an optimised background regimen (OBR) which included darunavir/ritonavir. **The indication in paediatric patients is based on 48-week analyses of a single-arm, Phase II trial in antiretroviral treatment-experienced paediatric patients (see section 5.1).“**

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.

² The text in bold represents the new or the amended indication.