22 March 2018
EMA/CHMP/37238/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Juluca

dolutegravir / rilpivirine

On 22 March 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Juluca, intended for the treatment of HIV infection. The applicant for this medicinal product is ViiV Healthcare UK Limited.

Juluca is a fixed-dose combination of two active substances, dolutegravir and rilpivirine (ATC code: J05AR21), and will be available as 50 mg/25 mg film-coated tablets. Dolutegravir inhibits HIV integrase by binding to the integrase active site and blocking the strand transfer step of retroviral DNA integration which is essential for HIV replication. Rilpivirine activity is mediated by non-competitive inhibition of HIV-1 reverse transcriptase.

The benefit with Juluca is its ability to maintain viral suppression of HIV strains that lack resistance (documented or clinically suspected) to integrase inhibitors. The most common side effects are insomnia, headache, dizziness, nausea and diarrhoea.

The full indication is: "Juluca is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults who are virologically-suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen for at least six months with no history of virological failure and no known or suspected resistance to any non-nucleoside reverse transcriptase inhibitor or integrase inhibitor (see section 5.1)."

It is proposed that Juluca 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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact