12 December 2024
EMA/559372/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Vocabria

cabotegravir

On 12 December 2024, 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 Vocabria. The marketing authorisation holder for this medicinal product is ViiV Healthcare BV.

The CHMP adopted an extension to the existing indication to include treatment of adolescents aged 12 years and older and weighing at least 35 kg.

The full indication for Vocabria prolonged-release suspension for injection will be as follows:[2]

> Vocabria injection is indicated, in combination with rilpivirine injection, for the treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection in adults **and adolescents (at least 12 years of age and weighing at least 35 kg)**, who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen without present or past evidence of viral resistance to, and no prior virological failure with agents of the non-nucleoside reverse transcriptase inhibitor (NNRTI) and integrase inhibitor (INI) class (see sections 4.2, 4.4 and 5.1).

The full indication for Vocabria film-coated tablets will be as follows:[2]

> Vocabria tablets are indicated, in combination with rilpivirine tablets, for the short-term treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection in adults **and adolescents (at least 12 years of age and weighing at least 35 kg)**, who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen without present or past evidence of viral resistance to, and no prior virological failure with agents of the non-nucleoside reverse transcriptase inhibitor (NNRTI) and integrase inhibitor (INI) class (see sections 4.2, 4.4 and 5.1) for:
>
> - Oral lead-in to assess tolerability of Vocabria and rilpivirine prior to administration of long acting cabotegravir injection plus long acting rilpivirine injection.

[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
[2] New text in bold

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

- Oral therapy for adults **and adolescents** who will miss planned dosing with cabotegravir injection plus rilpivirine injection.

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 made available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.