



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 February 2022
EMA/CHMP/107190/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Pifeltro doravirine

On 24 February 2022, 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 Pifeltro. The marketing authorisation holder for this medicinal product is Merck Sharp & Dohme B.V.

The CHMP adopted an extension to the existing indication as follows:²

Pifeltro is indicated, in combination with other antiretroviral medicinal products, for the treatment of adults, **and adolescents aged 12 years and older weighing at least 35 kg** infected with HIV-1 without past or present evidence of resistance to the NNRTI class (see sections 4.4 and 5.1).

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

² New text in bold.

