31 January 2020
EMA/CHMP/55713/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Tybost

cobicistat

On 30 January 2020, 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 Tybost. The marketing authorisation holder for this medicinal product is Gilead Sciences Ireland UC.

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

"Tybost is indicated as a pharmacokinetic enhancer of atazanavir 300 mg once daily or darunavir 800 mg once daily as part of antiretroviral combination therapy in human immunodeficiency virus-1 (HIV-1) infected adults **and adolescents aged 12 years and older:**

- **weighing at least 35 kg co-administered with atazanavir or**
- **weighing at least 40 kg co-administered with darunavir."**

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

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