15 December 2022
EMA/CHMP/916000/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Triumeq

dolutegravir / abacavir / lamivudine

On 15 December 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 Triumeq. The marketing authorisation holder for this medicinal product is ViiV Healthcare B.V.

The CHMP adopted the addition of a new pharmaceutical form (dispersible tablets) associated with a new strength (5 mg dolutegravir, 60 mg abacavir, and 30 mg lamivudine) suitable for children weighing from 14 to 25 kg. For information, the full indication for dispersible tablets will be as follows:[2]

> **Triumeq is indicated for the treatment of Human Immunodeficiency Virus (HIV) infected children weighing at least 14 kg to less than 25 kg.**
>
> **Before initiating treatment with abacavir-containing products, screening for carriage of the HLA-B*5701 allele should be performed in any HIV-infected patient, irrespective of racial origin. Abacavir should not be used in patients known to carry the HLA-B*5701 allele.**

The CHMP also adopted an extension to the indication for the film-coated tablets form to include treatment of children weighing at least 25 kg. For information, the full indication for film-coated tablets will be as follows:[2]

> Triumeq is indicated for the treatment of Human Immunodeficiency Virus (HIV) infected adults,- ~~and~~ adolescents **and children** ~~above 12 years of age~~ weighing at least **25** ~~40~~ kg.
>
> Before initiating treatment with abacavir-containing products, screening for carriage of the HLA-B*5701 allele should be performed in any HIV-infected patient, irrespective of racial origin. Abacavir should not be used in patients known to carry the HLA-B*5701 allele.

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

[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**, removed text as strikethrough

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(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.