25 April 2024
EMA/CHMP/136295/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Triumeq

dolutegravir / abacavir / lamivudine

On 25 April 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 Triumeq. The marketing authorisation holder for this medicinal product is ViiV Healthcare B.V.

The CHMP adopted an extension to the existing indication for Triumeq dispersable tablets to include children from 3 months of age and weighing at least 6 kg.

For information, the full indication will be as follows:[2]

> Triumeq is indicated for the treatment of Human Immunodeficiency Virus type 1 (HIV-1) infected children **of at least 3 months of age** weighing at least **6** ~~14~~ kg to less than 25 kg (see sections 4.4 and 5.1).
>
> 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 (see section 4.4). Abacavir should not be used in patients known to carry the HLA-B*5701 allele.

For information, the indication for Triumeq tablets remains unchanged and is provided in the summary of product characteristics (SmPC).

Detailed recommendations for the use of this product will be described in the updated 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.

[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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