30 January 2025
EMA/CHMP/31360/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Sivextro

tedizolid phosphate

On 30 January 2025, 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 Sivextro. The marketing authorisation holder for this medicinal product is Merck Sharp & Dohme B.V.

The CHMP adopted an extension to the existing indications for Sivextro film-coated tablets and Sivextro powder for concentrate for solution for infusion. For information, the full indications for Sivextro film-coated tablets will be as follows:[2]

> Sivextro **tablets** ~~is~~**are** indicated for the treatment of acute bacterial skin and skin structure infections (ABSSSI) in ~~adults and adolescents 12 years of age and older (see sections 4.4 and 5.1)~~:
>
> **- adults**
>
> **- adolescents and children weighing at least 35 kg.**
>
> **See sections 4.4 and 5.1.**
>
> Consideration should be given to official guidance on the appropriate use of antibacterial agents.

The full indications for Sivextro powder for concentrate for solution for infusion will be as follows:[2]

> Sivextro **powder for concentrate for solution for infusion** is indicated for the treatment of acute bacterial skin and skin structure infections (ABSSSI) **from birth** ~~in adults and adolescents 12 years of age and older~~ (see sections 4.4 and 5.1).
>
> Consideration should be given to official guidance on the appropriate use of antibacterial agents.

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

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

(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.