



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 January 2015
EMA/CHMP/46218/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Sivextro

tedizolid phosphate

On 22 January 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Sivextro, 200mg, film-coated tablet, powder for concentrate for solution for infusion intended for the treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults. The applicant for this medicinal product is Cubist (UK) Ltd. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Sivextro is tedizolid phosphate, a new oxazolidinone, which acts by inhibiting the protein biosynthesis in the bacterial cell, by binding to the 50S ribosomal subunit (ATC Code not yet assigned).

The benefits with Sivextro are its ability to be active against important Gram-positive pathogens that are common aetiological agents of ABSSSI, including methicillin-resistant *S. aureus* (including linezolid-resistant strains), as well as pathogenic streptococci. The most common side effects are nausea, headache, diarrhoea and vomiting.

A pharmacovigilance plan for Sivextro will be implemented as part of the marketing authorisation.

The approved indication is:

"Sivextro is indicated for the treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults (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 summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after 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.



The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Sivextro and therefore recommends the granting of the marketing authorisation.