21 November 2013
EMA/CHMP/709518/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Para-aminosalicylic acid Lucane

para-aminosalicylic acid

On 21 November 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Para-aminosalicylic acid Lucane, 4 g, gastro-resistant granules intended for the treatment of multi-drug resistant tuberculosis. Para-aminosalicylic acid Lucane was designated as an orphan medicinal product on 17 December 2010. The applicant for this medicinal product is Lucane Pharma SA. 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 Para-aminosalicylic acid Lucane is para-aminosalicylic acid (PAS), a bacteriostatic antimycobacterial (J04AA01). It exerts its activity by competing with paraminobenzoic acid (PABA) for dihydropteroate synthetase (DHP), a key enzyme in the biosynthesis of folates.

The benefits with Para-aminosalicylic acid Lucane are based on historical data showing that when PAS was used in combination with other anti-tuberculosis drugs (Streptomycin and Isoniazid), it could be effective in the treatment of active TB. It also appears to reduce the incidence of resistant organisms. It is therefore considered that PAS can make a contribution as part of a treatment regimen for MDR-TB (inclusive of XDR-TB). The most frequent adverse reactions were related to the gastrointestinal system (abdominal pain, vomiting, nausea, bloating, diarrhea and soft stools). Cutaneous hypersensitivity reactions were also frequent as well as adverse reactions related to the nervous system (giddiness, vestibular syndrome).

A pharmacovigilance plan for Para-aminosalicylic acid Lucane will be implemented as part of the marketing authorisation.

The approved indication is: “Para-aminosalicylic acid Lucane is indicated for use as part of an appropriate combination regimen for multi-drug resistant tuberculosis in adults and paediatric patients from 28 days of age and older when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability (see section 4.4).

[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.

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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.

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