23 September 2010
EMA/570279/2010
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

TOBI Podhaler

tobramycin

On 23 September 2010 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product TOBI Podhaler, 28mg, inhalation powder, hard capsules intended for the suppressive therapy of chronic pulmonary infection due to Pseudomonas aeruginosa in adults and children aged 6 years and older with cystic fibrosis. TOBI Podhaler was designated as an orphan medicinal product on 17 March 2003. The applicant for this medicinal product is Novartis Europharm 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 TOBI Podhaler is tobramycin, an aminoglycoside antibiotic (J01GB01) with bactericidal activity at concentrations equal to or slightly greater than inhibitory concentrations. Tobramycin acts primarily by disrupting protein synthesis leading to altered cell membrane permeability, progressive disruption of the cell envelope and eventual cell death. Tobramycin inhibits protein synthesis of numerous Gram-negative bacteria and is considered more active than most other aminoglycosides against Pseudomonas Aeruginosa.

The benefits with TOBI Podhaler are its ability to improve lung function in cystic fibrosis patients > 6 years of age with chronic pulmonary infection due to Pseudomonas aeruginosa, as shown by the relative increase from baseline in percent predicted FEV_1. It has shown additional benefits related to a faster and more convenient administration than tobramycin nebuliser solution.

The most common side effects are cough, lung disorder, productive cough, pyrexia, dyspnoea, oropharyngeal pain and dysphonia. The majority of the side effects reported with TOBI Podhaler were mild or moderate, and severity did not appear to differ between cycles.

Long-term efficacy and safety data are not available for TOBI Podhaler.

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

[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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The approved indication is: suppressive therapy of chronic pulmonary infection due to Pseudomonas aeruginosa in adults and children aged 6 years and older with cystic fibrosis. See sections 4.4 and 5.1 regarding data in different age groups. 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 will be 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 TOBI Podhaler and therefore recommends the granting of the marketing authorisation.