



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 December 2018
EMA/CHMP/862388/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Tobramycin PARI

tobramycin

On 13 December 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Tobramycin PARI, intended for the management of chronic pulmonary infection due to *Pseudomonas aeruginosa* in patients aged 6 years and older with cystic fibrosis. The applicant for this medicinal product is PARI Pharma GmbH.

Tobramycin PARI will be available as a 170 mg nebuliser solution. The active substance of Tobramycin PARI is tobramycin, an aminoglycoside antibiotic (ATC code: J01GB01) which primarily affects bacterial protein synthesis resulting in rapid concentration-dependent bacterial cell death.

Tobramycin PARI represents an alternative treatment option for cystic fibrosis patients with chronic *P. aeruginosa* lung infections.

It is a hybrid medicine² of TOBI Nebuliser solution which has been authorised in the EU since 10 December 1999. Tobramycin PARI contains the same active substance as TOBI Nebuliser solution, but has a different strength and is used with a different nebuliser device, allowing it to be inhaled over a shorter period. The most common side effects are cough and dysphonia.

The full indication is:

"Tobramycin PARI is indicated for the management of chronic pulmonary infection due to *Pseudomonas aeruginosa* in patients aged 6 years and older with cystic fibrosis (CF).

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

² Hybrid applications rely in part on the results of pre-clinical tests and clinical trials for a reference product and in part on new data.

