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**EPAR summary for the public**

# Vantobra

tobramycin



This is a summary of the European public assessment report (EPAR) for Vantobra. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Vantobra.

For practical information about using Vantobra, patients should read the package leaflet or contact their doctor or pharmacist.

## What is Vantobra and what is it used for?

Vantobra is an antibiotic used for treating long-term lung infection caused by the bacteria *Pseudomonas aeruginosa* in patients aged six years and older who have cystic fibrosis. Cystic fibrosis is an inherited disease in which there is an accumulation of thick mucus in the lungs that allows bacteria to grow more easily causing infections. *P. aeruginosa* is a frequent cause of infections in cystic fibrosis patients.

Before using Vantobra, doctors should consider official guidance on the appropriate use of antibiotics.

Vantobra is a 'hybrid medicine'. It contains the active substance tobramycin, which is the same active substance as that of the reference medicine, Tobi. Both medicines are available as a nebuliser solution. However, Vantobra differs from Tobi by having a higher concentration of the active substance and is inhaled using a different type of nebuliser.

## How is Vantobra used?

Vantobra is available as a nebuliser solution in single-dose containers called 'ampoules'. It can only be obtained with a prescription.

Vantobra is inhaled using a device called Tolero nebuliser, which converts the solution in the ampoule into a fine mist. The medicine is not to be inhaled with any other device.

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The recommended dose is one ampoule twice a day, ideally 12 hours apart. After 28 days of treatment, the patient stops treatment for 28 days, before starting another 28-day treatment. Treatment cycles may be repeated for as long as the doctor considers the patient to be benefiting from it.

If the patient is also receiving other inhaled treatments or chest physiotherapy, it is recommended that Vantobra is used last.

## How does Vantobra work?

The active substance in Vantobra, tobramycin, belongs to the group of antibiotics known as 'aminoglycosides'. It works by disrupting the production of proteins that *P. aeruginosa* needs to build its cell walls, resulting in damage to the bacteria, which eventually kills them.

## What benefits of Vantobra have been shown in studies?

Tobramycin has been used for several years to treat *P. aeruginosa* infection in patients with cystic fibrosis and the applicant submitted data from the literature to support the use of Vantobra.

In addition, the applicant conducted a 'bioequivalence' study in 58 patients with cystic fibrosis aged 6 years and above to determine whether Vantobra produces similar levels of the active substance in the body as the reference medicine, Tobi. The results of the study showed that Vantobra can be considered comparable to Tobi.

## What are the risks associated with Vantobra?

Side effects with Vantobra are not common. However, the following side effects are seen between 1 and 10 patients in 1,000: dyspnoea (difficulty breathing), dysphonia (hoarseness), pharyngitis (sore throat) and cough. For the full list of all side effects and restrictions, see the package leaflet.

## Why is Vantobra approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that Vantobra's benefits are greater than its risks and recommended that it be approved for use in the EU. The CHMP noted that inhaled tobramycin was the 'gold standard' for treating *P. aeruginosa* infection in patients with cystic fibrosis and that some patients cannot use the dry powder form because they cannot tolerate it. For these patients Vantobra, which is inhaled as a solution from a nebuliser, would be a useful alternative.

In addition, the time it takes to inhale Vantobra is shorter than for other tobramycin nebulisers and comparable to the time taken to inhale the dry powder. Vantobra therefore offers the advantage of better convenience and a higher likelihood of patients keeping to their treatment.

As regards safety, the Committee noted that safety profile of inhaled tobramycin was well known. There were no unusual safety findings with Vantobra.

## What measures are being taken to ensure the safe and effective use of Vantobra?

A risk management plan has been developed to ensure that Vantobra is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and

the package leaflet for Vantobra, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the summary of the risk management plan.

## Other information about Vantobra

The European Commission granted a marketing authorisation valid throughout the European Union for Vantobra on 18 March 2015.

The full EPAR and risk management plan summary for Vantobra can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Vantobra, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 03-2015.