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# Vantobra[1] (*tobramycin*)

An overview of Vantobra and why it is authorised in the EU

## 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 thick mucus builds up in the lungs that allows bacteria to grow more easily, causing infections. *P. aeruginosa* is a frequent cause of infections in cystic fibrosis patients.

Vantobra is a 'hybrid medicine'. This means that it is similar to a 'reference medicine' containing the same active substance, tobramycin; however, Vantobra has a higher amount of the active substance. The reference medicine for Vantobra is Tobi.

## How is Vantobra used?

Vantobra is available as a nebuliser solution in single-dose '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 recommended dose is one ampoule twice a day, ideally 12 hours apart. After a 28-day course of treatment, the patient stops treatment for 28 days, before starting another 28-day course. Treatment courses may be repeated for as long as the doctor considers the patient to be benefiting from treatment.

If the patient is also receiving other inhaled treatments or chest physiotherapy, it is recommended that Vantobra is used last. For more information about using Vantobra, see the package leaflet or contact your doctor or pharmacist.

[1] Previously known as Tobramycin PARI.

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## How does Vantobra work?

The active substance in Vantobra, tobramycin, belongs to the group of antibiotics known as 'aminoglycosides'. It works by interfering 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, a 'bioequivalence' study in 58 patients with cystic fibrosis aged 6 years and above determined 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 in up to 1 in 100 patients: dyspnoea (difficulty breathing), dysphonia (hoarseness), pharyngitis (sore throat) and cough. For the full list of side effects and restrictions, see the package leaflet.

## Why is Vantobra authorised in the EU?

The European Medicines Agency decided that Vantobra's benefits are greater than its risks and it can be authorised for use in the EU. The Agency 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 of unacceptable side effects. For these patients Vantobra, which is inhaled as a solution from a nebuliser, would be a useful alternative.

In addition, it takes less time to inhale Vantobra than other tobramycin nebulisers and the time it takes is comparable to the time it takes to inhale the dry powder. Vantobra is therefore easier to use and might help patients to stick to their treatment.

The Agency noted that safety profile of inhaled tobramycin was well known. There were no unexpected safety issues with Vantobra.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Vantobra have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Vantobra are continuously monitored. Side effects reported with Vantobra are carefully evaluated and any necessary action taken to protect patients.

## Other information about Vantobra

Vantobra received a marketing authorisation valid throughout the EU on 19 February 2019.

Further information on Vantobra can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/vantobra

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