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Tobramycin PARI (*tobramycin*)

An overview of Tobramycin PARI and why it is authorised in the EU

What is Tobramycin PARI and what is it used for?

Tobramycin PARI 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.

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

How is Tobramycin PARI used?

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

Tobramycin PARI 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 Tobramycin PARI is used last. For more information about using Tobramycin PARI, see the package leaflet or contact your doctor or pharmacist.

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How does Tobramycin PARI work?

The active substance in Tobramycin PARI, 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 Tobramycin PARI 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 Tobramycin PARI.

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

What are the risks associated with Tobramycin PARI?

Side effects with Tobramycin PARI 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 Tobramycin PARI authorised in the EU?

The European Medicines Agency decided that Tobramycin PARI'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 Tobramycin PARI, which is inhaled as a solution from a nebuliser, would be a useful alternative.

In addition, it takes less time to inhale Tobramycin PARI than other tobramycin nebulisers and the time it takes is comparable to the time it takes to inhale the dry powder. Tobramycin PARI 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 Tobramycin PARI.

What measures are being taken to ensure the safe and effective use of Tobramycin PARI?

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

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

Other information about Tobramycin PARI

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

Further information on Tobramycin PARI can be found on the Agency's website: https://www.ema.europa.eu/en/medicines/human/EPAR/tobramycin-pari

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