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EPAR summary for the public

Quinsair

levofloxacin

This is a summary of the European public assessment report (EPAR) for Quinsair. 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 Quinsair.

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

What is Quinsair and what is it used for?

Quinsair is an antibiotic used for treating long-term lung infection caused by the bacteria *Pseudomonas aeruginosa* in adults 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.

Quinsair contains the active substance levofloxacin. Before using Quinsair, doctors should consider official guidance on the appropriate use of antibiotics.

How is Quinsair used?

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

Quinsair is inhaled using a device called Zirela nebuliser system, which converts the solution in the ampoule into a fine mist. The medicine is not to be inhaled with any other device. 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 patient benefits.

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How does Quinsair work?

The active substance in Quinsair, levofloxacin, belongs to the group of antibiotics known as 'fluoroquinolones'. It works by blocking enzymes that *P. aeruginosa* bacteria use to make copies of their DNA during cell multiplication. By doing this, it stops the bacteria that are causing the infection from growing and multiplying.

Levofloxacin is a well-known antibiotic. Systemic formulations of levofloxacin (such as tablets and solutions for infusion) have been authorised in the EU since the 1990s.

What benefits of Quinsair have been shown in studies?

Quinsair has been investigated in two main studies in patients who had cystic fibrosis with *P. aeruginosa* lung infection. The first study, which involved 330 patients, compared Quinsair with placebo (a dummy treatment), while the second, involving 282 patients, compared it with another inhaled antibiotic (tobramycin). In both studies, the majority of patients were adults.

In the first study, Quinsair was shown to be better than placebo at improving the patients' forced expiratory volume in one second (FEV_1), adjusted for the patient's age, height and sex. FEV_1 is the most air a person can breathe out in one second. Following 28 days of treatment, the patients taking Quinsair had an improvement in FEV_1 of 1.73%, while for patients taking placebo the improvement in FEV_1 was of around 0.43%. However, the study failed to show that Quinsair is more effective than placebo at increasing the time it took before the patients had an exacerbation (flare-up) of their disease.

The second study showed that Quinsair was at least as good as tobramycin at improving FEV_1 following 1 to 3 treatment cycles.

What are the risks associated with Quinsair?

The most common side effects with Quinsair are cough (seen in 54% of patients), dysgeusia (taste disturbances, 30%) and tiredness/weakness (25%). For the full list of all side effects reported with Quinsair, see the package leaflet.

Quinsair must not be used in patients with epilepsy and those with a history of tendon disorders related to the use of fluoroquinolone antibiotics. It must not be used in pregnant or breastfeeding women. For the full list of restrictions, see the package leaflet.

Why is Quinsair approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Quinsair's benefits are greater than its risks and recommended that it be approved for use in the EU. The CHMP considered that the modest improvement in FEV_1 seen with Quinsair meant that it could help to meet the need for additional inhaled antibiotics to treat long-term *P. aeruginosa* infections in cystic fibrosis.

Regarding safety, Quinsair was well tolerated with side effects similar to those of levofloxacin given systemically (throughout the body). Because levofloxacin has a potential risk on cartilage, the use of the product was not considered justified in adolescents.

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

A risk management plan has been developed to ensure that Quinsair 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 Quinsair, including the appropriate precautions to be followed by healthcare professionals and patients.

In addition, the company that markets Quinsair will carry out a study to investigate the long-term safety of Quinsair when used in clinical practice in the European Union.

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

Other information about Quinsair

The European Commission granted a marketing authorisation valid throughout the European Union for Quinsair on 26 March 2015.

The full EPAR and risk management plan summary for Quinsair 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 Quinsair, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 04-2015.