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Quofenix (*delafloxacin*)

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

What is Quofenix and what is it used for?

Quofenix is an antibiotic used in adults to treat:

- bacterial infections of the skin and underlying tissues (acute bacterial skin and skin structure infections);
- community-acquired pneumonia (an infection of the lungs that is caught outside of hospital).

It is used when other medicines are not suitable. It contains the active substance delafloxacin.

How is Quofenix used?

Quofenix is available as a powder to be made into a solution for infusion (300 mg) and as tablets (450 mg). Quofenix is given by infusion (drip) into a vein over one hour every 12 hours. After starting with a drip, the doctor may decide to switch to a tablet by mouth once every 12 hours. Treatment is given for 5 to 14 days for acute bacterial skin and skin structure infections and 5 to 10 days for community acquired pneumonia.

Quofenix can only be obtained with a prescription and prescribers should take into account official guidance on the use of antibiotics.

For more information about using Quofenix, see the package leaflet or contact your doctor or pharmacist.

How does Quofenix work?

The active substance in Quofenix, delafloxacin, belongs to a group of antibiotics called fluoroquinolones. Fluoroquinolones work by preventing bacteria involved in skin infections and community-acquired pneumonia from making copies of their DNA (genetic material). As a result, the bacteria cannot multiply and they die. Quofenix has a different chemical structure to other fluoroquinolones, which means that it can enter bacterial cells more easily.

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What benefits of Quofenix have been shown in studies?

Quofenix was shown to be as effective as alternative antibiotics in two main studies of adults with acute bacterial skin and skin structure infections and one study in adults with community-acquired pneumonia. The main measure of effectiveness in these studies was whether the infection was cured.

In the first study involving 660 patients, Quofenix given into a vein was compared with vancomycin plus aztreonam (two other antibiotics), both given into a vein. After up to 14 days of treatment, 52% of patients treated with Quofenix were cured of their infection, compared with 51% of patients treated with vancomycin and aztreonam.

In the second study involving 850 patients, Quofenix given into a vein for 3 days and afterwards as tablets by mouth was compared with vancomycin plus aztreonam given into a vein. After treatment for up to 14 days, 58% of patients who received Quofenix were cured of their infection compared with 60% of patients who received vancomycin and aztreonam.

For community-acquired pneumonia, one study showed that after 5 to 10 days of treatment 91% of the patients receiving Quofenix were cured (342 out of 376), compared with 89% of the patients receiving moxifloxacin (330 out of 370).

What are the risks associated with Quofenix?

The most common side effects with Quofenix (which may affect up to 1 in 10 people) are diarrhoea, nausea (feeling sick) and hypertransaminasaemia (high blood levels of liver enzymes), which are mild to moderate.

Persistent and disabling side effects have occurred with fluoroquinolone antibiotics in some patients. Quofenix must not be used in patients who are hypersensitive (allergic) to quinolone or fluoroquinolone antibiotics or in patients who have had tendon disorders related to treatment with a fluoroquinolone antibiotic. It must not be used in women who are pregnant or breast feeding, or women who are able to have children and who are not using contraception. Quofenix must not be used in children or adolescents under 18 years of age.

For the full list of side effects and restrictions with Quofenix, see the package leaflet.

Why is Quofenix authorised in the EU?

The European Medicines Agency decided that Quofenix's benefits are greater than its risks and it can be authorised for use in the EU. Quofenix is as effective as alternative antibiotics given into a vein in treating acute bacterial skin and skin structure infections and offers the possibility of switching to treatment by mouth, which may be more convenient for the patient and could reduce hospitalisation costs. For the treatment of communityacquired pneumonia, Quofenix was as effective as other fluoroquinolones. Since Quofenix's safety profile was similar to that of other fluoroquinolones, it was considered that, as for other fluoroquinolones, it should be authorised for use only when other antibiotics are not suitable.

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

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

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

Other information about Quofenix

Quofenix received a marketing authorisation valid throughout the EU on 16 December 2019.

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

This overview was last updated in 03-2021.