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EPAR summary for the public

Zinforo

ceftaroline fosamil

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

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

What is Zinforo and what is it used for?

Zinforo is an antibiotic. It is used to treat the following infections in adults and children from two months of age:

- Complicated skin and soft tissue (tissue below the skin) infections. 'Complicated' means that the infection is difficult to treat.
- Community-acquired pneumonia (an infection of the lungs that is caught outside of hospital).

Prescribers should consider official guidance on the appropriate use of antibiotics.

Zinforo contains the active substance ceftaroline fosamil.

How is Zinforo used?

Zinforo is a powder that is made up into a solution for infusion (drip) into a vein.

In adults and adolescents from 12 to 18 years of age and weighing at least 33 kilograms, the recommended dose is 600 mg every 12 hours. In younger children from two months of age, and in children weighing less than 33 kilograms, the recommended dose depends on the weight of the patient. The infusion usually lasts 60 minutes, however for serious skin infections the doctor may have to give the infusion over 120 minutes.

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Patients with complicated skin and soft tissue infections should be treated for five to 14 days, whereas patients who have community-acquired pneumonia should be treated for five to seven days. In patients with moderately or severely reduced kidney function the doctor should reduce the dose.

The medicine can only be obtained with a prescription.

How does Zinforo work?

The active substance in Zinforo, ceftaroline fosamil, is a type of antibiotic called cephalosporin belonging to the group of 'beta-lactams'. It works by interfering with the production of complex molecules called 'peptidoglycans', which are essential components of bacterial cell walls. It does so by binding and blocking some enzymes called penicillin-binding protein transpeptidases involved in the last steps of bacterial cell wall production. This causes weakness in the bacterial cell walls which then become prone to collapse, ultimately leading to the death of the bacteria.

In experimental models Zinforo was shown to have activity against certain bacteria against which other antibiotics belonging to the beta-lactam class do not work (methicillin resistant *Staphylococcus aureus* (MRSA) and penicillin non-susceptible *Streptococcus pneumoniae* (PNSP)). The full list of bacteria against which Zinforo is active can be found in the summary of product characteristics (also part of the EPAR).

What benefits of Zinforo have been shown in studies?

Zinforo was shown to be as effective as other antibiotics in curing both skin and soft tissue infections and pneumonia in adults:

- In complicated skin and soft tissue infection, one study showed that 87% of the patients receiving Zinforo were cured (304 out of 351), compared with 86% of the patients receiving the combination of vancomycin and aztreonam (297 out of 347). In the second study, 85% of patients receiving Zinforo were cured (291 out of 342) compared with 86% of the patients receiving the combination of vancomycin and aztreonam (289 out of 338).
- In community-acquired pneumonia, one study showed that 84% of the patients receiving Zinforo were cured (244 out of 291), compared with 78% of the patients receiving ceftriaxone (233 out of 300). In another study, 81% of patients receiving Zinforo were cured (235 out of 289) compared with 76% of the patients receiving ceftriaxone (206 out of 273).

In children studies were carried out comparing Zinforo with other antibiotic treatments:

- In complicated skin and soft tissue infection, 94% of the patients receiving Zinforo were cured (101 out of 107), compared with 87% of those receiving vancomycin or cefazolin, with or without aztreonam (45 out of 52).
- In community acquired pneumonia that required hospital stay, 88% of the patients on Zinforo were cured (94 out of 107), compared with 89% of those receiving ceftriaxone.
- In a study in complicated community acquired pneumonia, 90% of the patients treated with Zinforo were cured, compared with 100% of those receiving ceftriaxone plus vancomycin.

What is the risk associated with Zinforo?

The most common side effects with Zinforo (seen in more than 3% of patients) are diarrhoea, headache, nausea (feeling sick) and pruritus (itching), which were generally mild or moderate in severity. For the full list of all side effects reported with Zinforo, see the package leaflet.

Zinforo must not be used in people who are hypersensitive (allergic) to ceftaroline fosamil or any of the other ingredients. Zinforo must also not be used in patients who are hypersensitive to other antibiotics belonging to the cephalosporin class and in patients who are severely allergic to other beta-lactam antibiotics. For the full list of restrictions, see the package leaflet.

Why has Zinforo been approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that Zinforo was effective in treating complicated skin and soft tissue infections and community-acquired pneumonia and was generally well tolerated in both adults and children. The risk of hypersensitivity was considered to be limited as treatment duration is relatively short. The CHMP noted that Zinforo had shown activity in experimental models against certain bacteria against which other antibiotics belonging to the beta-lactam class do not work, such as MRSA. However, as there were uncertainties about the effects of Zinforo in patients with certain very severe infections these effects will be investigated in further studies. The CHMP concluded that benefits of Zinforo are greater than its risks and recommended that it be given marketing authorisation.

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

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

Other information about Zinforo

The European Commission granted a marketing authorisation valid throughout the European Union for Zinforo on 23 August 2012.

The full EPAR for Zinforo 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 Zinforo, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 02-2017.