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Zinforo (*ceftaroline fosamil*)

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

What is Zinforo and what is it used for?

Zinforo is an antibiotic. It is used to treat adults and children (including newborn babies) who have:

- complicated infections of the skin and soft tissue (tissue below the skin). '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 given by infusion (drip) into a vein usually over 5 to 60 minutes. In adults and adolescents from 12 years of age weighing at least 33 kg, the usual dose is 600 mg every 12 hours. For some serious skin infections, the recommended dose is 600 mg every 8 hours, with each infusion lasting 120 minutes. In children and adolescents weighing less than 33 kilograms, the dose depends on the patient's weight.

Patients with complicated skin and soft tissue infections should be treated for 5 to 14 days and patients who have community-acquired pneumonia should be treated for 5 to 7 days.

The medicine can only be obtained with a prescription. For more information about using Zinforo, see the package leaflet or contact your doctor or pharmacist.

How does Zinforo work?

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

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In laboratory studies Zinforo was active against certain bacteria against which other antibiotics belonging to the beta-lactam class do not work (meticillin-resistant *Staphylococcus aureus* (MRSA) and penicillin non-susceptible *Streptococcus pneumoniae* (PNSP)).

What benefits of Zinforo have been shown in studies?

Studies in adults

Zinforo was as effective as other antibiotics in curing skin and soft tissue infections and pneumonia in adults.

In a study of patients with complicated skin and soft tissue infection, 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 a 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).

For 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).

Studies in children

In a children's study of complicated skin and soft tissue infection, 94% of the children 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).

Among children with community-acquired pneumonia that required hospital stay, 88% of those on Zinforo were cured (94 out of 107), compared with 89% of those receiving ceftriaxone.

Among those with complicated community-acquired pneumonia, 90% of the patients treated with Zinforo were cured, compared with 100% of those receiving ceftriaxone plus vancomycin.

What are the risks 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). For the full list of side effects of 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 is Zinforo authorised in the EU?

The European Medicines Agency concluded that Zinforo was effective in treating complicated skin and soft tissue infections and community-acquired pneumonia and its side effects in both adults and children were manageable. The Agency also noted that in laboratory studies Zinforo had shown activity against certain bacteria, such as MRSA, against which other beta-lactam antibiotics do not work. 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 Agency decided that Zinforo's benefits are greater than its risks and it can be authorised for use in the EU.

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.

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

Other information about Zinforo

Zinforo received a marketing authorisation valid throughout the EU on 23 August 2012.

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

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