21 June 2012
EMA/CHMP/405738/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Zinforo

Ceftaroline fosamil

On 21 June 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Zinforo, 600 mg, powder for concentrate for solution for infusion intended for treatment of adults with complicated skin and soft tissue infections (cSSTI) and community-acquired pneumonia (CAP). The applicant for this medicinal product is AstraZeneca AB. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Zinforo is ceftaroline fosamil, an oxyimino cephalosporin medicinal product (ATC Code J01DI02). As a cephalosporin, it acts as all beta-lactam agents via inhibition of the peptidoglycan synthesis.

With regard to benefits, in humans ceftaroline was shown to be non-inferior to the selected comparative regimens in four phase 3 studies – two studies in each of the approved indications (cSSTI and CAP). In addition, Zinforo has the ability to bind altered penicillin-binding-proteins of some resistant microorganisms such as methicillin-resistant *S.aureus* (MRSA) and penicillin-nonsusceptible *S.pneumoniae* (PNSP). The activity of ceftaroline against these microorganisms has been proven in nonclinical studies (*in vitro* and *in vivo* infection models), but clinical data are limited. The most common side effects are positive Coombs direct test, rash, pruritus, headache, dizziness, phlebitis, diarrhoea, nausea, vomiting, abdominal pain, increased transaminases, pyrexia and infusion site reactions (erythema, phlebitis, pain).

A pharmacovigilance plan for Zinforo will be implemented as part of the marketing authorisation.

The approved indication is: " Zinforo is indicated in adults for the treatment of the following infections (see sections 4.4 and 5.1):

- Complicated skin and soft tissue infections (cSSTI)
- Community-acquired pneumonia (CAP)

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

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Consideration should be given to official guidance on the appropriate use of antibacterial agents." Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Zinforo and therefore recommends the granting of the marketing authorisation.