EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 June 2019
EMA/CHMP/354371/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Zinforo

ceftaroline fosamil

On 27 June 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Zinforo. The marketing authorisation holder for this medicinal product is Pfizer Ireland Pharmaceuticals.

The CHMP adopted an extension to the existing indication as follows:[2]

> "Zinforo is indicated for the treatment of the following infections in ~~adults~~ **neonates, infants, children**~~,~~ ~~and~~ ~~children~~ **adolescents and adults** ~~from the age of 2 months~~ (see sections 4.4 and 5.1):
>
> - Complicated skin and soft tissue infections (cSSTI)
> - Community-acquired pneumonia (CAP)
>
> 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 updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

[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
[2] New text in bold, removed text as strikethrough

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