HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
SUMMARY
09 SEPTEMBER 2020
The legally binding text is the original French opinion version

ceftaroline
ZINFORO 600 mg powder for concentrate for solution for infusion

Indication extension

Key points

Favourable opinion for reimbursement in the treatment of complicated skin and soft tissue infections (cSSTI) in children from birth to 2 months of age.

What therapeutic improvement ?

Therapeutic improvement in management.

Role in the care pathway ?

In children, parenteral treatment is recommended in cellulitis with risk factors or signs of severity: an IV amoxicillin/clavulanic acid combination is the first-line treatment. This treatment should be combined with clindamycin in the event of skin infections with toxic shock syndrome, necrotising bacterial cellulitis or necrotising fasciitis, for which management is medical and surgical.

Antibiotic therapy should be adjusted following bacteriological identification. In the event of methicillin-resistant *Staphylococcus aureus* infection, vancomycin is the reference treatment.

Role of the medicinal product in the care pathway

ZINFORO (ceftaroline) may be proposed in healthcare-associated infections for which staphylococcal infection has been demonstrated or is suspected (suppurating infections) and for which methicillin resistance has been demonstrated or is strongly suspected, without any suggestion of previous colonisation with *Pseudomonas aeruginosa*. Although these are in the minority in cSSTI, it should be noted that ZINFORO has no activity on microorganisms such as *Pseudomonas aeruginosa* and anaerobes implicated in necrotising forms of infection.

Its prescription in the paediatric population should take into account the potential for an increased occurrence of adverse effects due to overexposure to drugs, particularly in neonates, infants, children and adolescents weighing less than 33 kg. A special warning has been added in sections 4.2 and 5.2 of the SPC.

COMMITTEE'S CONCLUSIONS

Considering all of this information and further to debate and voting, the Committee considers:

Clinical benefit

◗ Complicated skin and soft tissue infections are composed of a very varied range of clinical entities, for which the development conditions, treatment and prognosis are variable, from ulcers, infected wounds, abscesses, erysipelas and diabetic foot ulcers through to the most serious forms, including bacterial cellulitis and necrotising fasciitis.
◗ This proprietary medicinal product is part of a curative treatment regimen.
◗ The efficacy/adverse effects ratio of the medicinal product is high in moderately severe infections. In more serious forms requiring intensive care treatment and/or due to multi-drug resistant bacteria, the efficacy/adverse effects ratio is yet to be specified.
◗ There are alternative antibiotic therapies, including for multi-drug resistant bacteria.
◗ This proprietary medicinal product may be proposed in healthcare-associated skin infections for which infection with methicillin-resistant *Staphylococcus aureus* has been demonstrated or is suspected.

◗ Public health impact
Considering :
- the frequency and seriousness of the infections concerned,
- the medical need to have access to new antibiotics in order to respond to the spread of resistance to the antibiotics currently recommended in the treatment of these infections,
- the absence of efficacy data in more serious forms of cSSTI,

ZINFORO is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of ZINFORO (ceftaroline) is substantial in the treatment of complicated skin and soft tissue infections in children from birth to 2 months of age.

The Committee issues a favourable opinion for inclusion in the hospital formulary list of reimbursed proprietary medicinal products approved for use in the treatment of complicated skin and soft tissue infections in children from birth to 2 months of age.

Clinical Added Value

Considering :

- **the activity of ceftaroline on methicillin-resistant Staphylococcus and its non-inferior clinical efficacy to that of the vancomycin/aztreonam combination demonstrated in adults and children from the age of 2 months with a mild to moderate skin or soft tissue infection,**
- **a satisfactory safety profile comparable to that of the injectable cephalosporins currently marketed,**
- **a simplification of treatment compared to vancomycin (reduction in the number of injections and less monitoring),**

despite :

- **the absence of efficacy data and very limited safety data in children from birth to 2 months of age but taking into account clinical experience with ceftaroline in adults and children from the age of 2 months,**

the Committee considers that, in children from birth to 2 months of age, as in adults and children from 2 months of age, ZINFORO provides a minor clinical added value (CAV IV) in the treatment of complicated skin and soft tissue infections.