Translated from ***Rev Prescrire*** **September 2013; 33 (359): 657**

# ceftaroline fosamil

**NEW DRUG**

## Just another intravenous antibiotic


**Abstract**

● Various antibiotics, especially cephalosporins, are used for empirical treatment of community-acquired pneumonia requiring hospitalisation and intravenous treatment, and for serious infections of the skin and soft tissues. When the infection is caused by bacteria that are resistant to common antibiotics, some antibiotics such as *vancomycin* are available.

● *Ceftaroline* (Zinforo°, AstraZeneca) is a new cephalosporin intended for intravenous administration (as *ceftaroline fosamil*). It is authorised for the treatment of community-acquired pneumonia and for serious infections of the skin and soft tissues.

● In two double-blind, randomised trials of *ceftaroline* versus *ceftriaxone* (a cephalosporin), *ceftaroline* showed no advantage in patients with community-acquired pneumonia. Note that the results of these trials are undermined by the use of a suboptimal dose of *ceftriaxone*.

● *Ceftaroline* has not been evaluated versus a first-line treatment for serious skin infections. It has been compared with second-line antibiotics in patients with serious skin infections in four randomised trials. None of these trials showed that *ceftaroline* has superior efficacy.

● The known adverse effect profile of *ceftaroline* is similar to that of all cephalosporins, and comprises hypersensitivity reactions (including anaphylaxis) and gastrointestinal disorders (including rare cases of pseudomembranous colitis). A possible excess of haematological and renal adverse effects has also been raised.

● Given the absence of relevant data, it is best to avoid using *ceftaroline* during pregnancy.

● In practice, there is no proof that *ceftaroline* represents a therapeutic advance for patients with community-acquired pneumonia warranting hospitalisation or with serious skin or soft-tissue infections. It is best to stick with better-known antibiotics.




### NOTHING NEW

**There is no evidence that *ceftaroline* is more effective than tried and tested antibiotics used in patients with community-acquired pneumonia or serious skin or soft-tissue infections warranting hospitalisation. *Ceftaroline* has a similar adverse effect profile as other cephalosporins, possibly with a higher risk of haematological and renal adverse reactions. It is better to stick with established antibiotics.**

***Rev Prescrire*** **2013; 33 (359): 657.**

In response to our request for information, AstraZeneca provided us with published documents and packaging ikems.

Full review (5 pages, 15 references) available in French on request ***Rev Prescrire 2013; 33 (359): 657***.

## *ceftaroline fosamil*

**ZINFORO°**

Powder for solution to be diluted for infusion

• **600 mg** *ceftaroline fosamil* per vial

**antibiotic; cephalosporin**

■ **Indication:** *"(…) in adults (…) complicated skin and soft tissue infections (cSSTI) (…) community-acquired pneumonia (CAP)".*
[EU marketing authorisation, centralised procedure]"

## PRESCRIRE'S RATINGS

**Our judgement is based on the therapeutic advance of the new product.**
**It considers not only the inherent value of each product in terms of its risk-benefit balance, but also its advantages and disadvantages relative to existing products available in France. Note that the relative value of new products can vary from one country to another.**

**BRAVO:** The product is a major therapeutic advance in an area where previously no treatment was available.

**A REAL ADVANCE:** The product is an important therapeutic innovation but has certain limitations.

**OFFERS AN ADVANTAGE:** The product has some value but does not fundamentally change the present therapeutic practice.

**POSSIBLY HELPFUL:** The product has minimal additional value, and should not change prescribing habits except in rare circumstances.

**NOTHING NEW:** The product may be a new substance but is superfluous because it does not add to the clinical possibilities offered by previous products available. In most cases it concerns a me-too product.

**JUDGEMENT RESERVED:** The editors postpone their rating until better data and a more thorough evaluation of the drug are available.

**NOT ACCEPTABLE:** Product without evident benefit but with potential or real disadvantages.

## Quality of information from pharmaceutical companies

In response to our systematic requests

Company provided detailed information including unpublished data and packaging items.

Company provided information limited to administrative and published data.

Company provided minimal information, mainly administrative data.

Company provided no information.