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 communityacquired 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.

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]"

- 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 communityacquired pneumonia warranting hospitalisation or with serious skin or softtissue infections. It is best to stick with better-known antibiotics.

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NOTHING NEW



There is no evidence that ceftaroline is more effective than tried and tested antibiotics used

patients with community-acquired pneumonia or serious skin or softtissue 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.

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



Company provided information limited to administrative and published data.



Company provided minimal information, mainly administrative data.



Company provided no information.