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Press Office

Press release

European Medicines Agency advises doctors treating patients with nosocomial pneumonia with Doribax

Current dosing recommendations may not be enough for serious cases; no change in advice for all other approved indications

The European Medicines Agency has given new advice for the treatment of patients with nosocomial pneumonia, also known as hospital-acquired pneumonia, with Doribax (doripenem). A review of available data raises concerns that the currently approved dose of Doribax of 500mg every 8 hours may not be sufficient to treat all patients with nosocomial pneumonia, including ventilator-associated pneumonia.

Nosocomial pneumonia is caused by bacterial infection, and Doribax is one of a limited number of medicines available to treat this life-threatening disease.

For the treatment of patients with augmented renal clearance and/or with infections with non-fermenting gram-negative pathogens, the Agency's Committee for Medicinal Products for Human Use (CHMP) is recommending that doctors double the dose to 1g every 8 hours. The Committee also advises doctors that a longer treatment period (10-14 days) is required in patients with nosocomial pneumonia, including ventilator-associated pneumonia.

Doctors should exercise particular caution in patients for whom non-fermenting gram-negative pathogens such as *Pseudomonas aeruginosa* and *Acinetobacter* are suspected or confirmed as the cause of infection. In some of these patients, doctors should consider initiating concomitant treatment with an aminoglycoside antibiotic.

The review of Doribax was initiated following the early termination of a study by the marketing authorisation holder in patients with ventilator-associated pneumonia. The study tested a fixed 7-day treatment course with 1g Doribax against a fixed 10-day course with 1g of a comparator drug (imipenem/cilastatin). The study was stopped following a recommendation from an independent data monitoring committee because the patients treated with Doribax were less likely to recover than the patients in the comparator group.

Following a review of all available data, the Committee was of the opinion that the short, fixed duration of treatment with Doribax was a major contributor to the study outcome. The Committee also

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8427 **Facsimile** +44 (0)20 7418 8409
E-mail press@ema.europa.eu **Website** www.ema.europa.eu

considered that other factors such as augmented renal clearance (where the kidneys clear the medicine from the body too quickly) and infections involving specific types of bacteria may influence the effectiveness of treatment with Doribax in affected patients.

The Committee therefore concluded that the benefits of Doribax continue to outweigh its risks but recommended updating the prescribing information to allow using a higher dose in certain patients with hospital-acquired pneumonia and to clarify the recommendations and warnings on the use of Doribax in different types of bacterial infection.

A 'Dear Healthcare Professional Letter' will be sent to prescribers to inform them about the new advice.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. In addition to nosocomial pneumonia, Doribax is also used to treat complicated infections in the abdomen and the urinary tract. These indications were not affected by this review.
3. A European Commission decision on this opinion will be issued in due course.
4. The review of Doribax was conducted in the context of a formal review, initiated at the request of the European Commission under Article 20 of Regulation (EC) No 726/2004.
5. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

Contact our press officers

Monika Benstetter or Martin Harvey Allchurch

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu