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EPAR summary for the public

Doribax

doripenem

This is a summary of the European public assessment report (EPAR) for Doribax. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Doribax.

What is Doribax?

Doribax is a medicine containing the active substance doripenem. It is available as a powder to be made up into a solution for infusion (drip into a vein).

What is Doribax used for?

Doribax is an antibiotic. It is used to treat the following infections in adults:

- nosocomial pneumonia (an infection of the lungs). 'Nosocomial' means that the infection was caught in hospital, including pneumonia caused by the use of a ventilator (a machine that helps a patient to breathe);
- complicated infections in the abdomen. 'Complicated' means that the infection is difficult to treat;
- complicated infections of the urinary tract (the structures that carry urine).

Before using Doribax, doctors should consider official guidance on the use of antibiotics.

The medicine can only be obtained with a prescription.

How is Doribax used?

The standard dose of Doribax is 500 mg every eight hours. Each infusion lasts for one hour, although some patients with nosocomial pneumonia may need infusions lasting four hours. Treatment usually continues for between five and 14 days, depending on the type and severity of the infection and the

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patient's response (10 to 14 days are usually needed in nosocomial pneumonia). Because the medicine is removed from the body by the kidneys, the dose should be reduced in patients who have moderately or severely reduced kidney function. When treating nosocomial pneumonia, a dose of 1 g every eight hours infused over four hours may be considered for patients who have augmented renal clearance (where the kidneys clear the medicine from the body too quickly) or whose infection is caused by certain types of bacteria.

How does Doribax work?

The active substance in Doribax, doripenem, is an antibiotic that belongs to the group 'carbapenems'. It works by attaching to certain types of protein on the surface of the bacteria cells. This prevents the bacteria from building the walls that surround their cells, which kills the bacteria. The list of bacteria against which Doribax is active can be found in the summary of product characteristics (also part of the EPAR).

How has Doribax been studied?

Doribax has been studied in five main studies that compared Doribax with other antibiotics:

- two studies compared Doribax with piperacillin/tazobactam or imipenem in a total of 979 patients with nosocomial pneumonia;
- two studies compared Doribax with meropenem in a total of 962 patients with complicated infections in the abdomen;
- one study compared Doribax with levofloxacin in 753 patients with complicated urinary tract infections.

In all of the studies, the main measure of effectiveness was the number of patients whose infection was cured after treatment.

What benefit has Doribax shown during the studies?

Doribax was as effective as the other antibiotics in treating the infections:

- looking at the results of the two studies in nosocomial pneumonia taken together, 75% of the patients receiving Doribax were cured (195 out of 260), compared with 72% of the patients taking piperacillin/tazobactam or imipenem (174 out of 241);
- looking at the results of the two studies of complicated abdominal infections taken together, 85% of the patients receiving Doribax were cured (275 out of 325), compared with 84% of the patients receiving meropenem (260 out of 309);
- in complicated urinary tract infections, 82% of the patients receiving Doribax were cured (230 out of 280), compared with 83% of the patients receiving levofloxacin (221 out of 265).

What is the risk associated with Doribax?

The most common side effect with Doribax (seen in more than 1 patient in 10) is headache. For the full list of all side effects reported with Doribax, see the package leaflet.

Doribax must not be used in people who are hypersensitive (allergic) to doripenem or to other carbapenems. It must not be used in patients who are severely allergic to other 'beta-lactam' antibiotics, such as penicillins or cephalosporins.

Why has Doribax been approved?

The CHMP decided that Doribax's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Doribax

The European Commission granted a marketing authorisation valid throughout the European Union for Doribax on 25 July 2008.

The full EPAR for Doribax can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Doribax, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 07-2012.