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Questions and answers on Tienam and associated names (imipenem/cilastatin for infusion 500 mg/500 mg)

Outcome of a procedure under Article 30 of Directive 2001/83/EC

The European Medicines Agency has completed a review of Tienam. The Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that there is a need to harmonise the prescribing information for Tienam in the European Union (EU).

What is Tienam?

Tienam is an antibiotic used in complicated infections, generally in hospital. It has been used to treat infections of the lungs, the urinary tract (structures that carry urine), the abdomen, skin and the reproductive system. It can also be used in patients whose immune system is weakened when they have a fever.

Tienam contains two active substances: imipenem, which is an antibiotic belonging to the carbapenem family, and cilastatin, which is a 'dehydropeptidase inhibitor'. When Tienam is absorbed in the body, the imipenem component kills the bacteria that are causing the infection, while the cilastatin component blocks the dehydropeptidase enzyme in the kidney that normally breaks down imipenem. As a result, the antibiotic stays in the body and can work for longer.

The medicine is available in all EU Member States under the trade name Tienam, as well under other trade names: Conet, Imipem, Primaxin, Tenacid and Zienam. The company that markets these medicines is Merck, Sharp & Dohme.

Why was Tienam reviewed?

A company applied in the Netherlands for a generic version of Tienam in a decentralised procedure involving 16 Member States. During a decentralised procedure, the application submitted by the company is assessed by one Member State (the 'reference Member State', in this instance the Netherlands), with a view of granting a marketing authorisation that will be valid in this country as well as in other Member States (the 'concerned Member States'). While this process was ongoing, divergences across Member States were noted in the way Tienam can be used, as seen in the differences in the summaries of product characteristics (SmPCs), labelling and package leaflets. The



concerned Member States could not agree on the indications and on the recommendation for children under three years of age.

On 18 May 2009, the Dutch medicines regulatory agency referred the matter to the CHMP in order to harmonise the marketing authorisations for Tienam in the EU.

What are the conclusions of the CHMP?

The CHMP, in the light of the data submitted and the scientific discussion within the Committee, was of the opinion that the SmPCs, labelling and package leaflets should be harmonised across the EU.

The areas harmonised include:

4.1 Therapeutic indications

The CHMP agreed on the following indications:

- complicated intra-abdominal infections,
- severe pneumonia including hospital and ventilator-associated pneumonia,
- intra- and post-partum infections,
- complicated urinary tract infections,
- complicated skin and soft-tissue infections,
- use for fever in neutropenic patients when infection is suspected,
- treatment of bacteraemia (bacteria in the blood) that is associated with or suspected to be associated with the infections listed above.

The CHMP recommended that Tienam should not be used in some indications, such as meningitis, osteomyelitis (infection of the bones) and lung infection in cystic fibrosis patients. The CHMP also removed the use of Tienam in the prevention of infections.

4.2 Posology and method of administration

The CHMP harmonised the posology (the dose and frequency of dosing) in adults. For children, the CHMP recommended a harmonised dosage in children over one year of age, and made no dosage recommendations for children under one year of age because of a lack of data for this age group.

Other changes

The Committee also recommended harmonised wordings in other areas such as contra-indications, warnings and side effects.

The amended information to doctors and patients is available [here](#).

The European Commission issued a decision on this opinion on 10 March 2011.