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Questions and answers on Fortum and associated names (ceftazidime powder for solution for infusion or injection, 250 mg, 500 mg, 1 g, 2 g, 3 g)

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

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

What is Fortum?

Fortum is a medicine that contains the active substance ceftazidime. It is used to treat bacterial infections caused mainly by 'aerobic Gram-negative bacteria'.

The active substance, ceftazidime, is a 'beta-lactam' antibiotic of the group 'cephalosporins'. It works by attaching to proteins on the surface of bacteria. This prevents the bacteria from building their cell walls, and eventually kills them.

Fortum is also available in the EU under other trade names: Cefortam, Ceftim, Fortumset, Glazidim, Panzid, Potendal and Solvetan.

The company that markets these medicines is GlaxoSmithKline.

Why was Fortum reviewed?

Fortum is authorised in the EU via national procedures. This has led to divergences across Member States in the way the medicine can be used, as seen in the differences in the summaries of product characteristics (SmPCs), labelling and package leaflets in the countries where the medicine is marketed.

Fortum was identified as needing harmonisation by the Co-ordination Group on the Mutual and Decentralised Procedures – Human (CMD(h)).

On 24 March 2009, the European Commission referred the matter to the CHMP in order to harmonise the marketing authorisations for Fortum in the EU.

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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 that Fortum should be used to treat the following infections:

- nosocomial pneumonia (pneumonia caught in hospital)
- broncho-pulmonary infections (infection affecting the lungs) in patients with cystic fibrosis
- bacterial meningitis (inflammation of the membranes that surround the brain and spinal cord)
- chronic suppurative otitis media (infection of the middle ear with the formation of pus)
- malignant otitis externa (a severe infection of the outer ear and surrounding bone and tissue)
- complicated urinary tract infections
- complicated skin and soft tissue infections
- complicated intra-abdominal infections (infections within the abdomen)
- bone and joint infections
- peritonitis (inflammation of peritoneum lining the abdominal cavity) in patients undergoing 'continuous ambulatory peritoneal dialysis'.

Fortum may also be used to:

- treat bacteraemia (bacteria in the blood) that is associated with or suspected to be associated with the infections listed above;
- manage patients with neutropenia (with low levels of neutrophils, a type of white blood cell) who also have fever suspected to be caused by bacterial infection;
- prevent urinary tract infections for patients undergoing 'trans-urethral resection of the prostate (TURP)'.

When using Fortum, prescribers should take into account the fact that the medicine works mainly against aerobic Gram-negative bacteria. The medicine should therefore be used together with other antibacterial medicines if the infection is also thought to involve bacteria against which Fortum will not be effective.

4.2 Posology and method of administration

The Committee also agreed on specific dose ranges for adults and children for the various infections.

4.3 Contra-indications

Fortum should not be used in patients who are hypersensitive (allergic) to ceftazidime, to any other cephalosporin or to any other ingredients of the medicine. It must also not be used in patients with a history of severe hypersensitivity (allergic reactions) to any other type of beta-lactam antibiotics (penicillins, monobactams and carbapenems).

Other changes

The Committee also harmonised other sections of the SmPC including the sections on special warnings and pregnancy and lactation.

The amended information to doctors and patients is available here.

A European Commission decision on this opinion will be issued in due course.