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Questions and answers on Tazocin and associated names (piperacillin and tazobactam, 2/0.25 g and 4/0.5 g powder for solution for infusion)

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

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

What is Tazocin?

Tazocin is a medicine that contains the active substances piperacillin and tazobactam. It is used to treat a wide range of bacterial infections.

Piperacillin is an antibiotic that belongs to the group 'beta-lactams'. It works by attaching to proteins on the surface of bacteria. This prevents the bacteria from building their cell walls, and eventually kills them.

Tazobactam blocks the action of bacterial enzymes called beta-lactamases. Beta-lactamases break down beta-lactam antibiotics such as piperacillin, making the bacteria resistant to these medicines. By blocking the action of beta-lactamases, tazobactam stops bacteria from being resistant to piperacillin, thereby making piperacillin more effective at killing them.

Tazocin is also available in the EU under other trade names: Tazobac, Tazocel, Tazocilline and Tazonam.

The company that markets these medicines is Pfizer.

Why was Tazocin reviewed?

Tazocin 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.

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

On 12 June 2009, the European Commission referred the matter to the CHMP in order to harmonise the marketing authorisations for Tazocin 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 that Tazocin should be used to treat the following infections in adults and adolescents:

- severe pneumonia (infection of the lungs), including infections acquired in hospital or by patients on a mechanical ventilator
- complicated urinary tract infections, including pyelonephritis (kidney infection)
- complicated intra-abdominal infections (infections within the abdomen)
- complicated skin and soft tissue infections, including diabetic foot infections.

Tazocin can also be used in adults to treat bacteraemia (bacteria in the blood) that is associated with or suspected to be associated with the infections listed above.

Tazocin can be used to treat complicated intra-abdominal infections in children aged from two to 12 years.

Tazocin may also be used to manage children, adolescents and adults with neutropenia (low levels of neutrophils, a type of white blood cell) who also have fever suspected to be caused by bacterial infection.

4.2 Posology and method of administration

In adults and adolescents the usual dose is 4 g piperacillin /0.5 g tazobactam given every eight hours. For severe pneumonia and bacterial infections in neutropenic patients, the recommended dose is 4 g piperacillin /0.5 g tazobactam given every six hours.

The dose for children is 80 mg piperacillin /10 mg tazobactam per kilogram body weight every six hours for neutropenic children and 100 mg piperacillin /12.5 mg tazobactam per kg body weight every eight hours for children with complicated intra-abdominal infections.

Other sections

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

The amended information to doctors and patients is available here.

The European Commission issued a decision on 21 February 2011.