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

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

On 23 January 2014, the European Medicines Agency completed a review of Rocephin. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that there is a need to harmonise the prescribing information for Rocephin in the European Union (EU).

What is Rocephin?

Rocephin is a medicine that contains the active substance ceftriaxone. It is an antibiotic used to treat a wide range of bacterial infections including pneumonia (infection of the lungs) and meningitis (infection of the membranes around the brain and spine). Ceftriaxone belongs to 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.

Rocephin is marketed in the following EU Member States: Belgium, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Luxembourg, Malta, the Netherlands, Portugal, Romania, Sweden and the United Kingdom, as well as Iceland. It is also available in the EU under other trade names: Rocefin, Rocephalin, Rocephalin cum lidocain, Rocephine.

The company that markets these medicines is Roche.

Why was Rocephin reviewed?

Rocephin 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.

Rocephin was identified as needing harmonisation by the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh).

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On 9 December 2011, the European Commission referred the matter to the CHMP in order to harmonise the marketing authorisations for Rocephin 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 Rocephin should no longer be used to treat sinusitis (inflammation of the sinuses), pharyngitis (sore throat) and prostatitis (inflammation of the prostate, a gland of the male reproductive system) because not enough clinical data are available to support these indications. The CHMP concluded that Rocephin should be used to treat the following infections in adults and children, which were already approved in several but not all EU Member States:

- bacterial meningitis;
- hospital- and community-acquired pneumonia (infection of the lungs caught in or outside the hospital);
- acute otitis media (infection of the middle ear);
- intra-abdominal infections (infections within the abdomen);
- complicated urinary tract infections, including pyelonephritis (kidney infection);
- infections of bones and joints;
- complicated skin and soft tissue infections;
- the sexually transmitted infections gonorrhoea and syphilis;
- bacterial endocarditis (an infection in the heart).

Rocephin may be used to treat acute exacerbations (flare-ups) of chronic obstructive pulmonary disease in adults. It may also be used to treat disseminated Lyme borreliosis (a bacterial infection spread to humans by infected ticks) in adults and children including neonates from 15 days of age.

Rocephin may be used to manage patients with neutropenia (low levels of neutrophils, a type of white blood cell) who also have fever suspected to be caused by bacterial infection, patients with bacteraemia (when the bacteria are detected in the blood) suspected to be caused by any of the infections mentioned above, and for the pre-operative prevention of surgical site infections.

4.2 Posology and method of administration

Having harmonised the indications, the CHMP also harmonised the recommendations on how to use Rocephin in adults and children. Rocephin should preferably be given into a vein by injection over a period of 5 minutes or by infusion (drip) over at least 30 minutes, or else by deep intramuscular injection.

In adults and children over 12 years of age, the recommended dose varies between 1 and 4 g of Rocephin once daily depending on the condition it is used to treat. In children below 12 years of age, the recommended dose of Rocephin depends on body weight and the condition it is used to treat.

Other changes

The CHMP also harmonised other sections of the SmPC including section 4.3 (contraindications), 4.4 (special warnings and precautions for use) and 4.6 (pregnancy and lactation).

The amended information to doctors and patients is available here.

The European Commission issued a decision on 21 March 2014.