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Questions and answers on Amoxil and associated names (amoxicillin)

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

On 25 June 2015, the European Medicines Agency completed a review of Amoxil. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that there was a need to harmonise the prescribing information for Amoxil in the European Union (EU).

What is Amoxil?

Amoxil is an antibiotic used to treat a wide range of bacterial infections. It contains the active substance amoxicillin which belongs to the 'beta-lactam' family (the family that includes penicillins). It works by attaching to proteins on the surface of bacteria. This prevents the bacteria from building their cell walls, and eventually kills them.

Amoxil is marketed in the following EU Member States: Belgium, Cyprus, France, Greece, Ireland, Latvia, Lithuania, Luxembourg, Malta, Portugal, Spain and the United Kingdom. In some countries it is available under the trade names Amoxicilline Biogaran and Clamoxyl.

The company that markets these medicines is GlaxoSmithKline.

Why was Amoxil reviewed?

Amoxil has been 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.

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

On 22 July 2013, the European Commission referred the matter to the CHMP in order to harmonise the marketing authorisations for Amoxil 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 the oral (to be taken by mouth) formulations of Amoxil (such as capsules, tablets and suspensions) can be used in adults and children for the treatment of the following bacterial infections:

- Acute bacterial sinusitis (infection of the sinuses);
- Acute otitis media (infection of the middle ear);
- Acute streptococcal tonsillitis and pharyngitis (infections of the tonsils and throat);
- Acute exacerbations (flare-ups) of chronic bronchitis (inflammation of the airways in the lungs);
- Community acquired pneumonia (infection of the lungs acquired outside the hospital);
- Acute cystitis (infection of the bladder);
- Asymptomatic bacteriuria (bacteria detected in the urine) in pregnancy;
- Acute pyelonephritis (kidney infection);
- Typhoid and paratyphoid fever;
- Dental abscess with spreading cellulitis (inflammation of the deep skin tissue);
- Prosthetic joint infections;
- *Helicobacter pylori* eradication;
- Lyme disease.

Oral Amoxil can also be used for the prevention of endocarditis (infection of the inner lining of the heart).

Amoxil is also available as a solution for injection or infusion (drip) into a vein, and as a solution for injection into a muscle. These formulations can be used to treat adults and children with the following bacterial infections:

- Severe infections of the ear, nose and throat (such as mastoiditis, peritonsillar infections, epiglottitis, and sinusitis when accompanied by severe systemic signs and symptoms);
- Acute exacerbations of chronic bronchitis;
- Community acquired pneumonia;
- Acute cystitis;
- Acute pyelonephritis;
- Severe dental abscess with spreading cellulitis;
- Prosthetic joint infections;
- Lyme disease;

- Bacterial meningitis (infection of the membranes around the brain and spine);
- Bacteraemia (bacteria detected in the blood) that occurs in association with, or is suspected to be associated with, any of the infections listed above.

The injectable formulations can also be used for the treatment and prevention of endocarditis.

The CHMP also agreed that Amoxil should no longer be used to treat female genital infections, because not enough clinical data are available to support this indication. Additionally, Amoxil should no longer be used in several other indications (treatment of bronchitis, acute lung disease, urethritis (inflammation of the urethra, the tube that carries urine from the bladder out of the body), gonococcal infections, male genital infections, gonorrhoea (a sexually transmitted infection caused by bacteria called *Neisseria gonorrhoeae*), enteritis (inflammation of the small intestine) with bacteraemia and intra-abdominal infections such as peritonitis, cholecystitis and acute cholangitis, and serious infections caused by *Haemophilus influenzae*). This is either because antibiotics are no longer used to treat these conditions, or because other antibiotics have been shown to be more effective than amoxicillin.

4.2 Posology and method of administration

Having harmonised the indications, the CHMP also harmonised the recommendations on how to use Amoxil. The recommended dose of Amoxil varies depending on the infection it is used to treat, the way it is given, and the age and weight of the patient. Doses range from 250 mg to 2 g two or three times a day for adults and children weighing more than 40 kilograms, and from 20 to 200 mg per kilogram per day for children weighing less than 40 kilograms.

4.3 Contraindications

The CHMP agreed that Amoxil must not be used in patients who are hypersensitive (allergic) to amoxicillin or any other ingredients of Amoxil, and to any of the penicillins. Additionally, Amoxil must not be used in patients who have had severe allergic reactions to another type of beta-lactam antibiotic (e.g. a cephalosporin, carbapenem or monobactam).

Other changes

The Committee also harmonised other sections of the SmPC including sections 4.4 (special warnings and precautions for use), 4.6 (fertility, pregnancy and lactation), and 4.8 (side effects).

The amended information to doctors and patients is available here.

A decision on this opinion was issued by the European Commission on 20/08/2015.