

Summary of Product Characteristics

1. TRADE NAME OF THE MEDICINAL PRODUCT

Oramox (Amoxicillin Oral Suspension BP) 125mg/5ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

When prepared as directed Each 5ml of solution contains Amoxicillin Trihydrate BP/Ph Eur. equivalent to 125mg of Amoxicillin.

Each 5ml of dose contains 2862.5 mg of sucrose and 3.79 mg of sodium

For full list of excipients, see Section 6.1

3. PHARMACEUTICAL FORM

Powder for oral suspension.

A pale yellow crystalline powder for oral suspension with the odour and flavour of lemon.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

A broad-spectrum antibiotic for use in the treatment of infections due to organisms sensitive to amoxicillin. Amoxicillin is also indicated in the oral prophylaxis of endocarditis related to dental procedures, and in treatment of uncomplicated gonorrhoea.

4.2 Posology and method of administration

Adults and children over 10 years old: The usual dosage is 250mg three times daily. In cases of severe infection the dosage may be doubled.

Oral prophylaxis: A single dose of 3g prior to the dental procedure.

In the treatment of uncomplicated gonorrhoea a single dose of 3g may be used.

Children under 10 years old: The usual children's dosage is half the adult dosage.

Oral prophylaxis in children under 10 years old: A single dose of 1 to 1.5g prior to the dental procedure.

In patients with renal insufficiency, the total daily dosage may need to be reduced if excretion of the drug is delayed.

4.3 Contra-indications

Use in patients with hypersensitivity to penicillins, including ampicillin, or to cephalosporins.

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4.4 Special warnings and special precautions for use

Prolonged use of anti-infective agent may result in the development of superinfection by non-susceptible organisms.

Patients with infectious mononucleosis frequently develop rashes with ampicillin therapy. A similar tendency may be apparent with amoxicillin.

4.5 Interactions with other medicaments and other forms of interaction

Probenecid retards the renal excretion of amoxicillin. Concurrent use of penicillins (including amoxicillin) with methotrexate, can reduce the clearance of methotrexate from the body.

4.6 Pregnancy and lactation

Although animal studies and experience to-date in human pregnancy have shown no teratogenic effects, amoxicillin should not be used during pregnancy unless considered essential by the physician. Amoxicillin is excreted in breast milk, presenting the risk of candidiasis and of central nervous system toxicity due to prematurity of the blood-brain barrier. There is a theoretical possibility of later sensitisation.

4.7 Effects on ability to drive and use machines

No effect.

4.8 Undesirable effects

Amoxicillin is generally well-tolerated. Possible side-effects include urticaria, macular and maculopapular skin rashes, nausea, vomiting and diarrhoea. In common with other beta-lactam antibiotics, angioedema and anaphylaxis have been reported. Pseudomembranous colitis has been reported rarely.

4.9 Overdose

Gross overdosage will produce very high urinary concentrations. Provided that an adequate fluid intake and urinary output are maintained, problems are unlikely to occur, although crystalluria is a possibility. More specific measures may be required in patients with impaired renal function. Amoxicillin is removed by haemodialysis.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Amoxicillin is a semisynthetic antibiotic, an analogue of ampicillin, with a broad spectrum of bactericidal activity against many gram-positive and gram-negative micro-organisms. It acts by inhibiting bacterial cell-wall synthesis.

5.2 Pharmacokinetic properties

Amoxicillin is resistant to inactivation by gastric acid and is rapidly absorbed after oral administration, reaching peak plasma concentrations 1 to 2 hours later.

About 20% of amoxicillin is protein bound in plasma. Amoxicillin is widely distributed in body tissues and fluids. It is metabolised to a limited extent and is excreted in urine. The plasma half-life of amoxicillin is 1 to 1.5 hours, but may be more prolonged in renal failure.

5.3 Preclinical safety data

No further information other than that which is included in the Summary of Product Characteristics.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Benzoate E211
Disodium Edetate
Sodium Citrate Anhydrous
Lemon Flavour Powder
Quinoline Yellow E104
Sucrose

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

Shelf life as packaged for sale: 2 years.

Shelf life after reconstitution: 7 days

6.4 Special precautions for storage

Powder: Do not store above 25°C. Store in the original package. Keep the bottle tightly closed.

Suspension: After mixing the suspension should be stored at 2°C - 8°C in a refrigerator.

6.5 Nature and contents of container

Amber glass bottles with a screw cap packed in an outer carton.

Natural high-density polyethylene bottle with a tamper evident cap packed in an outer carton.

Pack sizes: 60 ml and 100 ml.

Not all pack sizes may be marketed.

6.6 Instructions for use/handling

To prepare, reconstitute to the mark with 38mls (for pack size of 60ml) or 64mls (for pack size of 100ml) of water. Shake until all powder is dispersed.

After reconstitution the product appears as a yellow solution with the odour and flavour of lemon.

7. MARKETING AUTHORIZATION HOLDER

Antigen Pharmaceuticals Ltd.
Roscrea
Co. Tipperary

8. MARKETING AUTHORIZATION NUMBER

PA 73/113/3

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF AUTHORIZATION

Date of first PA : 27/9/88

Date of last Renewal: 27/9/98

10. DATE OF (PARTIAL) REVISION OF THE TEXT

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