

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Oramox 500 mg Hard Capsules.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains Amoxicillin Trihydrate equivalent to 500 mg of anhydrous Amoxicillin.

For a full list of excipients, see Section 6.1

3 PHARMACEUTICAL FORM

Capsules, hard
(short term: capsules)

Size 0 hard gelatin capsules with deep yellow opaque caps and ivory opaque bodies, marked 'Oramox 500' and containing an off-white granular powder.

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.

4.3 Contraindications

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

4.4 Special warnings and 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 Interaction with other medicinal products 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

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

Magnesium Stearate,
Maize Starch.

Capsule Body
Red Iron Oxide E172
Yellow Iron Oxide E172
Titanium Dioxide E171
Gelatin

Capsule Cap
Yellow Iron Oxide E172
Titanium Dioxide E171
Gelatin

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years

6.4 Special precautions for storage

Do not store above 25°C.
Store in the original package to protect from light and moisture.
Keep the container tightly closed.

6.5 Nature and contents of container

Polypropylene securitainers with tamper evident polypropylene caps.
Pack sizes: 50, 100 and 500 capsules.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Antigen Pharmaceuticals Ltd
Chandler House
Roscrea
Co Tipperary
Ireland

8 MARKETING AUTHORISATION NUMBER

PA 0073/113/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27 September 1988

Date of last renewal: 27 September 2008

10 DATE OF REVISION OF THE TEXT

August 2009