IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PA0408/012/001
Case No: 2038775

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Ranbaxy Ireland Limited

Spafield, Cork Road, **Cashel**, **Co. Tipperary**, **Ireland**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Rimoxallin (Amoxicillin Oral Suspension BP) 125mg/5ml Powder for Oral Suspension

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **06/11/2007**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Rimoxallin (Amoxicillin Oral Suspension BP) 125 mg/5 ml Powder for Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml of reconstituted suspension contains 125 mg of amoxicillin (as trihydrate).

Excipients: also includes sucrose, 2.59g per 5ml.
For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral suspension.

Pale-yellow powder which when reconstituted with the specified volume of water produces a yellow suspension with a sweet lemon flavour and odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the treatment of infections due to organisms sensitive to Amoxicillin and in the oral prophylaxis of endocarditis related to dental procedures, and acute uncomplicated gonorrhoea.

4.2 Posology and method of administration

Treatment
Adults and Children over 10 years of age:
The usual total daily dosage is 750mg in three divided doses. In the treatment of uncomplicated gonorrhoea a single dose of 3g may be used.

Children: 6-10 years:
The usual total daily dose is 375-750mg in divided doses.

Children: 2-5 years:
375mg daily in divided doses.

Children under 2 years:
100-300mg daily in divided doses.
Dosage may be doubled in cases of severe infection.

Prophylaxis:
Adults:
A single dose of 3g prior to the dental procedure.

Children:
A single dose of 1 to 1.5g prior to the procedure.

In patients with renal insufficiency total daily dosage may need reduction if excretion of drug is delayed.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

Prolonged use of an anti-infective agent may result in superinfection by organisms resistant to that anti-infective.

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

When concomitantly administered with oral contraceptives, the contraceptives may have a reduced effect.

4.6 Pregnancy and lactation

This product should not be used during pregnancy unless considered essential by the physician. Amoxicillin is excreted in breast milk presenting the risk of candidiasis. There is also a theoretical possibility of later sensitisation.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Side effects include gastrointestinal upset, including nausea, vomiting and diarrhoea. Macular, maculopapular rashes and urticaria may occur.

4.9 Overdose

None stated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Amoxicillin is bactericidal and resembles benzylpenicillin in its action against gram-positive organisms including *Streptococcus faecalis, streptococcus pneumonia* and haemolytic streptococci.

It is also effective against gram-positive organisms particularly *Haemophilis influenzae, Salmonella* and most strains of *Escherichia coli*. *Neisseria gonorrhoea, N. meningitidis, Bacillus pertussis, Proteus mirabilis* and *Brucella* spp. are also sensitive.

Amoxicillin has been reported to be slightly more active against more *Streptococci* and *Salmonella* spp. than Ampicillin, but less active against *Shigella* spp. Amoxicillin is inactivated by penicillinase and complete cross resistance has been reported between Amoxicillin and Ampicillin.

5.2 Pharmacokinetic properties

A broad spectrum antibiotic, well absorbed after oral administration, reaching peak levels 1-2 hours later, and excreted in the urine.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium benzoate
Sodium citrate
Colloidal anhydrous silica
Dispersible cellulose
Saccharin sodium
Lemon powder flavour
Quinoline yellow (E104)
Sucrose

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

Unreconstituted product: 2 years
Reconstituted product: 14 days

6.4 Special precautions for storage

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

For the reconstituted suspension: Store in a refrigerator (2°C to 8°C).

6.5 Nature and contents of container

HDPE, tamper-evident bottle with polypropylene tamper-evident lids: 100 ml & 60 ml.
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

100ml: Add 59ml of water, replace the cap and shake the bottle vigorously. The reconstituted suspension is yellow in colour with a sweet lemon flavour and odour.

60ml: Add 36ml of water, replace the cap and shake the bottle vigorously. The reconstituted suspension is yellow in colour with a sweet lemon flavour and odour.

7 MARKETING AUTHORISATION HOLDER

Ranbaxy Ireland Ltd.
Spafield, Cork Road
Cashel
County Tipperary

8 MARKETING AUTHORISATION NUMBER

PA 408/12/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th November 1987
Date of last renewal: 6th November 2007

10 DATE OF REVISION OF THE TEXT

October 2007