IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0408/012/003
Case No: 2038778

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 250 mg Hard Capsules

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 **08/04/2008**.

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 250 mg Hard Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains amoxicillin trihydrate equivalent to 250 mg of amoxicillin.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule, hard.

Size 2, hard gelatin capsules consisting of a scarlet cap and buff body, marked ‘RIMOX 250’.

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

Oral tablet.

Treatment:
Adults:
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.

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

None stated.

4.6 Pregnancy and lactation

The product should not be used during pregnancy unless considered essential by the physician. Amoxicillin is excreted in breast milk, presenting the risk of candidiasis in the body and also 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

None stated.

4.8 Undesirable effects

Side effects, as with other penicillins, are uncommon and mainly of a mild and transitory nature.

Hypersensitivity reactions:
Skin rash, pruritis and urticaria have been reported occasionally. Rarely, skin reactions such as erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, bullous and exfoliative dermatitis and acute generalised exanthematous pustulosis (AGEP) have been reported.

If any hypersensitivity occurs, treatment should be discontinued.

As with other antibiotics, severe allergic reactions including angioneurotic oedema, anaphylaxis (see section 4.4), serum sickness and hypersensitivity vasculitis have been reported.

Interstitial nephritis can occur rarely.

Gastrointestinal reactions:
Effects include nausea, vomiting and diarrhoea. Mucocutaneous candidiasis and antibiotic associated colitis including pseudomembranous colitis and haemorrhagic colitis have been reported rarely.

Hepatic effects:
A moderate rise in AST and/ or ALT have been occasionally noted but the significance of this is unclear. As with other beta-lactam antibiotics, hepatitis and cholestatic jaundice have been reported very rarely.

Haematological effects:
As with other beta-lactams, reversible leucopenia (including severe neutropenia or agranulocytosis), reversible thrombocytopenia and haemolytic anaemia have been reported rarely. Prolongation of bleeding time and prothrombin time have also been reported rarely.

CNS effects:
CNS effects have been seen rarely. They include hyperkinesias, dizziness and convulsions. Convulsions may occur inpatients with impaired renal function or in those receiving high doses.

4.9 Overdose

None stated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Amoxicillin is a broad spectrum antibiotic.

5.2 Pharmacokinetic properties

Amoxicillin is well absorbed after oral administration, reaching peak levels 1-2 hours later, and excreted in urine with a $T_{1/2}$ of 1-2 hours.

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

Colloidal anhydrous silica
Magnesium stearate

Capsule shell components:
Body:
Red iron oxide (E172)
Yellow iron oxide (E172)
Titanium dioxide (E171)
Gelatin

Cap:
Erythrosine (E127)
Indigotine (E132)
Titanium dioxide (E171)
Gelatin

Composition of Ink:
Shellac
Activated charcoal
Soya lecithin MC Thin
Dimeticone
Black iron oxide (E172)

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. Keep the container tightly closed.

6.5 Nature and contents of container

White polypropylene/polyethylene containers with tamper evident closures.
1000, 500, 100 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

Ranbaxy Ireland Ltd.
Spafield
Cork Road
Cashel
County Tipperary

8 MARKETING AUTHORISATION NUMBER

PA 408/12/3

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th April 1988
Date of last renewal: 8th April 2008

10 DATE OF REVISION OF THE TEXT

April 2008