IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0408/001/004
Case No: 2054055

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

Rimacillin 250 mg/5 ml 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 **06/11/2008**.

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

Rimacillin 250 mg/5 ml Powder for Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

When reconstituted, each 5 ml contains 250 mg ampicillin (as the trihydrate).
Each 5ml dose also includes 0.25 mg of amaranth (E123) and 2.63 g of sucrose.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral suspension.
Pale-pink powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the treatment of infections due to organisms sensitive to Ampicillin.

4.2 Posology and method of administration

To be taken orally.
After reconstitution powder forms a pink suspension with a cherry taste and odour.

Adults and children over 20kg body weight:

The usual dose is 250mg every six hours.

Children under 20kg body weight:

50 to 100mg/kg per day in divided doses.

4.3 Contraindications

Use in patients with hypersensitivity to penicillins, including Ampicillin.

4.4 Special warnings and precautions for use

Prolonged use may result in the development of supra infection due to organisms resistant to Ampicillin.

Patients with infectious mononucleosis are particularly prone to develop rashes with Ampicillin.

Amaranth Red may cause allergic reactions.

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

4.6 Pregnancy and lactation

Anti-infectives should not be used during pregnancy or lactation unless considered essential by the physician. Ampicillin has been shown to cross the placenta and is excreted in breast milk. Studies in animals and experience of human use to date have shown no evidence of teratogenic effects.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Side effects include maculo papular rashes, urticaria and other evidence of hypersensitivity, gastrointestinal disturbances and diarrhoea.
Transiently raised liver enzymes occur occasionally and pseudo membranous colitis has been reported in a few cases.

4.9 Overdose

Problems of overdosage with Ampicillin are unlikely to occur; if encountered they may be treated symptomatically.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Ampicillin is a broad spectrum antibiotic and is better able to penetrate the outer membrane of some gram negative bacteria. It is also a beta lactam antibiotic. Ampicillin is used for the treatment of infections due to organisms sensitive to this drug. Rapidly dividing bacteria are most susceptible to the action of penicillins.

5.2 Pharmacokinetic properties

Ampicillin is well absorbed after oral administration, reaching peak levels 1 to 2 hours later, excreted in bile and urine with a $T_{1/2}$ of 1-2 hours. It is relatively stable in the acid gastric secretion. Food can interfere with the absorption of Ampicillin so doses should preferably be taken at least 30 minutes before meals. There is little diffusion of Ampicillin into the cerebrospinal fluid except when the meninges are inflamed. About 20% is bound to plasma proteins.

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
Microcrystalline cellulose
Saccharin sodium
Cherry flavour IFF

Amaranth red (E123)
Sucrose

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

Unopened: 18 months.
After reconstitution: 7 days.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package.
Keep the container tightly closed. Store reconstituted suspension in the refrigerator (2°C to 8°C).

6.5 Nature and contents of container

Amber glass bottles with ROPP screw caps.
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

To reconstitute, add 40 ml (60 ml bottle) or 67 ml (100 ml bottle) of water and shake the bottle.

7 MARKETING AUTHORISATION HOLDER

Ranbaxy Ireland Limited
Spafield
Cork Road
Cashel
County Tipperary

8 MARKETING AUTHORISATION NUMBER

PA 408/1/4

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisaiton: 06 November 1987
Date of last renewal: 06 November 2007

10 DATE OF REVISION OF THE TEXT

November 2008