

IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0408/001/002

Case No: 2055825

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 500 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 **30/09/2008**.

Signed on behalf of the Irish Medicines Board this

A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Rimacillin 500 mg Hard Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 500 mg ampicillin (as the trihydrate).

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Hard capsule.

Size 0, hard, gelatin capsules with a scarlet body and a grey cap overprinted 'Rima 500'.

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.

Adults and children over 20kg body weight:

The usual dose is 250mg every six hours.

For treatment of severe infections, the dosage may be increased at the discretion of the physician.

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.

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

Symptoms of overdose are hypersensitivity reactions, including skin rashes, acute anaphylactic shock with circulatory collapse and obstruction of breathing due to oedema and spasm of the bronchi. Serum sickness may occur and is characterised by fever, urticarial skin eruptions, generalised oedema, multiple joint effusions and enlargement of spleen and lymph glands. This syndrome is rare and may occur up to 1-2 weeks after overdose. Other hypersensitivity reactions are vasculitis, interstitial nephritis, and various haematological disturbances. Gastro-intestinal disturbances and diarrhoea may occur. 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

Magnesium stearate
Colloidal anhydrous silica

Capsule Shell Components

Body:

Red iron oxide (E172)

Erythrosine (E127)
Titanium dioxide (E171)
Gelatin

Cap:
Black 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. Keep the container tightly closed.

6.5 Nature and contents of container

White polypropylene containers with tamper evident closures.
20, 100, 250, 500 and 1000 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 Limited
Spafield
Cork Road
Cashel
County Tipperary

8 MARKETING AUTHORISATION NUMBER

PA 408/1/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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

10 DATE OF REVISION OF THE TEXT

September 2008