Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Rimasal Salbutamol Tablets BP 4mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Salbutamol Sulphate Ph. Eur. equivalent to 4 mg Salbutamol.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Tablet.

Circular, convex, pink tablets embossed ‘R4’ on one side and a breakline on the other.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As a Beta-adrenergic stimulant for the relief of bronchospasm such as occurs with asthma, bronchitis, emphysema.

4.2 Posology and method of adminstration

For oral administration

Adults:
The usual total daily dose is 12 to 32mg in three or four divided doses.

However in the elderly patient or the patient particularly responsive to these agents, the initial dosage should be 2mg three or four times daily.

Children:
Aged over 12 years: The usual total daily dose is 6 to 8mg in divided doses.
Aged 6 to 12 years: The usual total daily dose is 6 to 8mg in divided doses.
Aged 2 to 6 years: The usual total daily dose is 3 to 8mg in divided doses.

4.3 Contraindications

Use in patients with a known hypersensitivity to the sympathomimetics.

4.4 Special warnings and precautions for use

Caution should be used in patients suffering from angina, severe tachycardia or thyrotoxicosis.

Use with caution in diabetic patients as this product may cause an increase in blood sugar levels.

4.5 Interaction with other medicinal products and other forms of interaction

Caution should be exercised in its use with anaesthetic agents such as chloroform, cyclopropane, halothane and other halogenated agents.

Salbutamol should not cause difficulty in micturition because unlike sympathomimetic drugs such as ephedrine, it does not stimulate α-adrenoceptors. However, there have been reports of difficulty in micturition in patients with prostatic enlargement.

The effects of this product may be altered by guanethidine, reserpine, methyldopa, tricyclic antidepressants and monoamine oxidase inhibitors.

4.6 Pregnancy and lactation

Salbutamol should only be used during pregnancy if considered essential by the physician.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Salbutamol causes peripheral vasodilation which may result in reflex tachycardia and increased cardiac output.

4.9 Overdose

Symptoms and treatment:

Symptoms: Peripheral vasodilation and a compensatory small increase in heart rate; occasionally headaches.

Treatment: Preferably a cardio-selective beta-blocking agent is used but beta-blocking drugs should be used with caution in patients with a history of bronchospasm.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Relatively selective β_2-adrenergic stimulant.

5.2 Pharmacokinetic properties

It is well absorbed from the gut and undergoes first pass metabolism in the liver. Plasma half-life is approximately 5 hours and excretion is predominantly through the kidney.

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

Lactose monohydrate
Ponceau 4R
Starch paste 15%
Sodium Starch Gylcollate (Type A)
Magnesium stearate
Maize Starch

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years

6.4 Special precautions for storage

Do not store above 25°C. Keep in the original container. Keep container tightly closed. Protect from light.

6.5 Nature and contents of container

Polypropylene/polyethylene containers and tamper evident closures.
1000, 500 and 100 tablets.

6.6 Instructions for use and handling

No special precautions required.

7 MARKETING AUTHORISATION HOLDER

Ranbaxy Ireland Ltd.
Spafield
Cork Road
Cashel
Co. Tipperary
Ireland

8 MARKETING AUTHORISATION NUMBER

PA 408/18/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7th April 1988
Date of last renewal: 7th April 2003

10 DATE OF REVISION OF THE TEXT

May 2003