

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Bendroflumethiazide Tablets BP 5mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Bendroflumethiazide 5.0 mg

For excipients, see 6.1

3 PHARMACEUTICAL FORM

White circular biconvex tablet with a breakline on one side and embossed "RIMA" on the other side.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As a diuretic in the management of oedema such as arise from cardiac, renal or hepatic origin, toxaemia or pregnancy, corticosteroid administration.

4.2 Posology and method of administration

For oral administration only.

Adults:

The usual initial dose is 5-10mg as a single dose, with a maintenance dosage of 2.5-10mg daily, preferably in the morning.

4.3 Contraindications

Use of this product in the presence of hypokalaemia, pre-coma associated with hepatic cirrhosis or Addison's disease.

4.4 Special warnings and special precautions for use

Patients who are being treated with this preparation require regular supervision with monitoring of fluid and electrolyte state to avoid inadequate potassium supplementation or excessive loss of fluid. The preparation should only be used with particular caution in elderly patients, or those with potential obstruction of the urinary tract, or with disorders rendering their electrolyte balance precarious. Hyperuricaemia and gout may be induced by this preparation.

4.5 Interaction with other medicinal products and other forms of interaction

The concomitant administration of this preparation with cardiac glycosides or hypotensive agents may necessitate adjustment of the dosage of these drugs.

The preparation may induce hyperglycaemia particularly in patients with latent diabetes, and may necessitate adjustment of control by hypoglycaemic agents in cases of diabetes mellitus.

Concurrent use with lithium salts may increase toxicity.

4.6 Pregnancy and lactation

The preparation 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

Side effects may include skin rashes, gastric irritation, dizziness, headache.

4.9 Overdose

Following overdose, empty the stomach by emesis or lavage and apply symptomatic treatment. Treatment should be directed at fluid and electrolyte replacement.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Bendroflumethiazide is a thiazide diuretic which reduces the reabsorption of electrolytes from the renal tubules, thereby increasing the excretion of sodium and chloride ions, and consequently of water. Potassium ions are excreted to a lesser extent. Its inhibitory action on carbonic anhydrase is weak, but carbonic anhydrase activity is reduced so that bicarbonate excretion is increased, but this effect is generally small compared with the effect on chloride excretion and does not appreciably alter the acid base balance on the pH of the urine. The thiazides, like Bendroflumethiazide, also have a slightly lowering effect on blood pressure and enhance the effect of other antihypertensive agents.

Paradoxically, they have an antidiuretic effect in patients with diabetes insipidus. Bendroflumethiazide inhibits lactation and should be avoided in nursing mothers. When treatment is prolonged, or in susceptible patients, loss of potassium may be sufficient to produce hypokalaemia (potassium supplements should then be given).

5.2 Pharmacokinetic properties

Bendroflumethiazide is a thiazide diuretic, well absorbed from the gastro-intestinal tract, excreted unchanged in the urine usually within 24 hours.

5.3 Preclinical safety data

Clinical trials have not been carried out because this product is one with an established use which has been adequately tested on human beings so that its effects, include side effects, are already known.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose
Magnesium Stearate
Sodium Starch Glycollate

6.2 Incompatibilities

None stated.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25°C. Keep container tightly closed.

6.5 Nature and contents of container

White polypropylene containers
1000, 500, 250, 100 tablets.

6.6 Instructions for use and handling

None stated.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PA 408/30/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24th February 1992

Date of last renewal: 24th February 2002

10 DATE OF REVISION OF THE TEXT

June 2005