

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Rowatanal Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 g contains Bismuth Subgallate 2g, Zinc Oxide 8g, Menthol 1g.

Excipients with known effect

Each 100g contains 20g wool fat, glycerol and 0.3g parahydroxybenzoates.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream.

A light yellow, smooth cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As an adjunct in the symptomatic relief of uncomplicated haemorrhoids and anal irritation.

4.2 Posology and method of administration

Route of Administration: Rectal Perianal.

Recommended Dosage Schedule

Adults only

The cream should be applied 2-3 times daily and after defaecation. For internal haemorrhoids use the cannula nozzle provided.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Haemorrhoids or rectal bleeding are an indication to seek the doctor's advice. If your condition persists or worsens, you should also seek your doctor's advice.

Glycerol may have a slight laxative effect and wool fat may cause local skin reactions (e.g. contact dermatitis).

Parahydroxybenzoates may cause allergic reactions (possibly delayed).

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

This product should not be used in pregnancy and lactation unless considered essential by the physician.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Side effects have been reported rarely with use of this and similar products. Side effects include a transient, cooling sensation on application of the cream. Sensitivity reactions have been reported very rarely.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2. Tel: +353 1 6764971. Fax: +353 1 6762517. Website: www.hpra.ie. e-mail: medsafety@hpra.ie

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: CO5AX: Cardiovascular

System: Vasoprotectives

Other: Antihemorrhoidals for topical use.

Bismuth compounds have been used for the astringent and anti-diarrhoeal properties in a variety of gastro-intestinal disorders and have been applied topically in skin disorders and ano-rectal disorders such as haemorrhoids.

Zinc Oxide is mildly astringent and is used topically as a soothing and protective application in eczema and slight excoriations in wounds and for haemorrhoids.

When applied to the skin Menthol dilates the blood vessels, causing a sensation of coldness followed by an analgesic effect. It relieves itching and is used in creams, lotions or ointments in pruritus and urticaria.

5.2 Pharmacokinetic properties

Poorly soluble Bismuth compounds are largely converted to insoluble Bismuth Oxide, hydroxide and oxychloride in the stomach. Most Bismuth compounds are only slightly absorbed, with the absorbed portion excreted mainly in the urine. Some Bismuth is retained in the bones and tissues and some is excreted in the faeces. Bismuth can cross the placenta.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium carbonate

Hard Paraffin

Polyoxyethylene-12-cetyl stearyl alcohol

Glycerol-mono-dioleate

Glycerol

Wool fat

Nipastat (ethyl hydroxybenzoate (E214), methyl hydroxybenzoate (E218), propyl hydroxybenzoate (E216) and butyl hydroxybenzoate)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Three Years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Rowatanal Cream is packed in enamel coated, white, cylindrical 26g aluminium tubes with a white polyethylene or polypropylene screw cap. A white cannula nozzle is included for use in internal haemorrhoids.

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

ROWA PHARMACEUTICALS LTD.

Bantry

Co. Cork

Ireland

8 MARKETING AUTHORISATION NUMBER

PA0074/016/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 9th May 1996

Date of last renewal: 9th May 2006

10 DATE OF REVISION OF THE TEXT

February 2017