SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Boots Haemorrhoid Ointment or Haemorrhoid Relief Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients	%w/w	Specification
Lidocaine	0.6	Ph Eur
Zinc oxide	6.6	Ph Eur

3 PHARMACEUTICAL FORM

Rectal ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

This product is indicated for the relief of pain and discomfort of haemorrhoids and pruritis ani.

4.2 Posology and method of administration

HAEMORRHOIDS

Adults, children over 12 years and elderly: This product should be applied night

and morning and after each bowel movement. Repeat as required.

EXTERNAL PILES

Moisten cotton wool with warm water and gently cleanse the sore area. Carefully dry with fresh cotton wool and apply approximately 1 inch (2.5 cm) of this product.

INTERNAL PILES

Remove cap of tube. Screw the nozzle supplied to the top of the tube. Apply a little ointment to the outside of the nozzle for greater comfort. Insert nozzle into anal opening and gently squeeze ointment inside. This is easier to do if you bend forward.

PRURITIS ANI

Adults, children over 12 years and elderly: This product should be applied when required.

4.3 Contraindications

Hypersensitivity to any of the ingredients, especially lidocaine.

4.4 Special warnings and precautions for use

Do not use if you are sensitive to any of the ingredients. Keep all medicines out of the reach of children. For external use only.

Constipation should be avoided as it may aggravate the symptoms. For further advice consult your pharmacist.

If symptoms persist for more than 14 days talk to your doctor.

Not recommended for pregnant women or children under the age of 12 years except on medical advice.

Side effects are rare with this medication but if anything unusual happens seek medical advice.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically significant interactions are known.

4.6 Pregnancy and lactation

The safety of this product in pregnancy and lactation has not been established, but is not thought to constitute a hazard, though caution should be exercised during the first trimester.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Hypersensitivity reactions to any of the ingredients, particularly lidocaine. Occasionally may cause diarrhoea.

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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

4.9 Overdose

In view of the nature of the presentation of this product, accidental or deliberate overdosage is highly unlikely. In the event of overdosage, this will initially produce excessive anaesthesia of the upper gastrointestinal tract. Treatment of potential overdosage should be symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Lidocaine has a local anaesthetic action, which relieves pain and discomfort in the affected areas. Zinc oxide applied externally has a mild astringent action on the skin.

5.2 Pharmacokinetic properties

Lidocaine is readily absorbed from mucous membranes. The plasma elimination half-life is about two hours.

Lidocaine undergoes significant first pass metabolism in the liver and is rapidly de-ethylated to the active metabolite monoethylglycine-xylidide and then hydrolysed to various metabolites including glycine xylidide. Less than 10% is excreted unchanged in the kidneys. The metabolites are also excreted in the urine.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Yellow soft paraffin

Light liquid paraffin

Colloidal anhydrous silica

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months, northern temperate regions.

6.4 Special precautions for storage

Do not store above 25^{o}C.

6.5 Nature and contents of container

An internally lacquered aluminium tube with a gasket and a polyethylene or polypropylene screw cap. The pack is supplied with a screw-on rectal applicator.

Pack sizes: 25g, 55g

6.6 Special precautions for disposal

EXTERNAL PILES

Moisten cotton wool with warm water and gently cleanse the sore area. Carefully dry with fresh cotton wool and apply approximately 1 inch *(2.5* cm) of this product.

INTERNAL PILES

Remove cap of tube. Screw the nozzle supplied to the top of the tube. Apply a little ointment to the outside of the nozzle for greater comfort. Insert nozzle into anal opening and gently squeeze ointment inside. This is easier to do if you bend forward.

7 MARKETING AUTHORISATION HOLDER

The Boots Company PLC
1 Thane Road West
Nottingham
NG2 3AA
ENGLAND

8 MARKETING AUTHORISATION NUMBER(S)

PL 00014/0448

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

11th May 1995

10 DATE OF REVISION OF THE TEXT

22/07/2016