

1 NAME OF THE MEDICINAL PRODUCT

Anodesyn Ointment
Care Haemorrhoid Relief Ointment
Sainsburys Haemorrhoid Relief Ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Allantoin 0.5% w/w.
Lidocaine Hydrochloride Monohydrate 0.5% w/w.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

A soft white translucent ointment.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

For the symptomatic relief of pain and irritation associated with external haemorrhoids.

4.2. Posology and method of administration

Route of administration: For external application.

Adults & the elderly.

For external piles, wash the affected area with tepid water, dry and apply the ointment with gauze or lint.

Repeat as required, do not use for more than 7 days unless advised by your doctor.

Children.

Not recommended for children.

4.3. Contraindications

Hypersensitivity to any of the ingredients, especially lidocaine.

4.4 Special warnings and precautions for use

Anodesyn Ointment / Care Haemorrhoid Relief Ointment / Sainsburys Haemorrhoid Relief Ointment is intended for use for short periods and should not be used for longer than 7 days without medical advice. Patients should be instructed to seek medical advice if they experience persistent pain or bleeding from the anus, especially where associated with a change in bowel habit, if the stomach is distended or if they are losing weight.

Avoid contact with the eyes.

The label will state:

Keep all medicines out of the reach and sight of children.

If symptoms persist for more than 7 days consult your doctor.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically significant drug interactions known.

4.6 Fertility, pregnancy and lactation

The safety of Anodesyn Ointment / Care Haemorrhoid Relief Ointment / Sainsburys Haemorrhoid Relief Ointment in pregnancy and lactation has not been assessed, but it is thought unlikely to constitute a hazard, though caution should be exercised during the first trimester.

Lidocaine crosses the placenta and is distributed into breast milk.

4.7 Effects on ability to drive and use machines

No or negligible influence.

4.8 Undesirable effects

Hypersensitivity to any of the ingredients, especially lidocaine.

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

Accidental ingestion may result in anaesthesia of the upper respiratory tract, nausea, vomiting and abdominal discomfort. Ingestion of very large quantities could result in CNS and cardiovascular toxicity. Treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

C05A X - Other antihaemorrhoidals for topical use

Lidocaine has a local anaesthetic action, relieving pain and discomfort in the affected areas.

Allantoin is claimed to promote healing.

5.2 Pharmacokinetic properties

No data available.

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

White Soft Paraffin

Wool Fat

Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Three years.

6.4 Special precautions for storage

Store at or below 25°C.

6.5 Nature and contents of container

A collapsible 25g aluminium tube, internally lacquered with a latex welt and HPDE screw cap. Supplied with a nozzle and packed in a carton.

6.6 Instructions for use/handling

None stated

7. MARKETING AUTHORISATION HOLDER

Thornton & Ross Limited
Linthwaite
Huddersfield
West Yorkshire
HD7 5QH
United Kingdom

8. MARKETING AUTHORISATION NUMBER

PL 00240/0072

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

2nd December 2002

10 DATE OF REVISION OF THE TEXT

05/07/2021