

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1 NAME OF THE MEDICINAL PRODUCT**

Anodesyn Suppositories  
Sainsburys Haemorrhoid Relief Suppositories  
Boots Haemorrhoid Relief Suppositories

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Allantoin	10.25mg
Lidocaine Hydrochloride Monohydrate	10.25mg

For the full list of excipients, see section 6.1.

### **3. PHARMACEUTICAL FORM**

Suppositories

White or nearly white suppositories.

### **4. CLINICAL PARTICULARS**

#### **4.1. Therapeutic indications**

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

#### **4.2. Posology and method of administration**

Route of administration: For rectal administration.

Adults and the elderly.

If necessary empty the bowels before using the suppository. Remove the protective film and insert the suppository as deep as possible into the rectum. One suppository should be inserted night and morning after each bowel movement. 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 Suppositories/Boots Haemorrhoid Suppositories /Sainsburys Haemorrhoid Relief Suppositories are 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.

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 Interactions with other medicinal products and other forms of interaction**

No clinically significant drug interactions known.

#### **4.6 Pregnancy and Lactation**

The safety of Anodesyn Suppositories/Boots Haemorrhoid Suppositories /Sainsburys Haemorrhoid Relief Suppositories in pregnancy and lactation has not been established, 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, 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](http://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 D01 - Products containing local anaesthetics

Lidocaine has a local anaesthetic action, relieving pain and discomfort in the affected areas. Allantoin is claimed to promote healing.

### **5.2 Pharmacokinetic properties**

Not applicable

### **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 PROPERTIES**

### **6.1. List of excipients**

Colloidal Anhydrous Silica  
Witepsol W35  
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 white polythene lined, unplasticised PVC moulded strip, heat sealed and placed into a printed carton, containing 6, 12 or 24 suppositories.

**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 00240/0071

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

6<sup>th</sup> September 2002

**10 DATE OF REVISION OF THE TEXT**

05/07/2021