

# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Germoloids Cream

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Zinc oxide Ph. Eur. 6.6% w/w

Lidocaine hydrochloride Ph. Eur. 0.7% w/w

## 3 PHARMACEUTICAL FORM

Cream for topical and rectal administration.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

The symptomatic relief of pain, swelling, irritation and itching associated with haemorrhoids and pruritus ani.

### 4.2 Posology and method of administration

Adults and children aged 12 years and over:

Apply at least twice a day with a minimum of three to four hours between applications. Further applications can be made at any time of day and are particularly recommended after bowel movement.

Do not use more than four times in any 24 hour period.

External piles and pruritus ani:

Apply to the affected area.

Internal piles:

Gently insert applicator into the anal opening and expel a small amount of the cream by squeezing the tube gently.

Children under 12 years:

Only as directed by a doctor.

The elderly:

Use as per adult directions.

**4.3 Contraindications**

Hypersensitivity to any of the constituents.

**4.4 Special warnings and precautions for use**

Persons who continually suffer from haemorrhoids or who have severe haemorrhoids or who experience excessive bleeding, are advised to consult a doctor.

**4.5 Interaction with other medicinal products and other forms of interaction**

None known for topical preparations

**4.6 Pregnancy and lactation**

There is a lack of definitive evidence of safety of the product in human pregnancy and lactation. However, lidocaine hydrochloride and zinc oxide have been in wide use for many years without apparent ill consequence. It is not necessary to contraindicate this product in pregnancy and lactation provided caution is exercised and the directions for use are followed. However, as with all medicines, the advice of a doctor should be sought.

**4.7 Effects on ability to drive and use machines**

None

**4.8 Undesirable effects**

Very rarely increased irritation may occur at the site of application.

**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**

It is very unlikely that overdosage would occur from this pharmaceutical form. Symptoms of lidocaine overdosage would be unlikely to occur even after anal insertion of 25g of cream.

Normally there should be no systemic adverse effects, but at worst CNS and cardiovascular effects are possible. Treatment would be symptomatic after withdrawal of product.

In the case of accidental oral ingestion, the advice of a doctor should be sought.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Zinc oxide has astringent, antiseptic, soothing and protective properties.

Lidocaine hydrochloride has a local anaesthetic action.

The cream base has emollient properties.

### **5.2 Pharmacokinetic properties**

The product has a local action with minimal risk of systemic effects. Lidocaine has a fast onset and intermediate duration of action. It is partially absorbed but plasma levels will be low in view of the concentration of lidocaine in the product. It undergoes de-ethylation in the liver where clearance approaches the rate of hepatic flow.

### **5.3 Preclinical safety data**

Preclinical safety data on these active ingredients in the literature, have not revealed any pertinent and conclusive findings which are of relevance to the recommended dosage and use of the product.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Polawax  
White soft paraffin  
Methyl salicylate  
Methyl hydroxybenzoate  
Butyl hydroxybenzoate  
Purified water.

### **6.2 Incompatibilities**

None known

### **6.3 Shelf life**

Three years

#### **6.4 Special precautions for storage**

Store below 25°C.

#### **6.5 Nature and contents of container**

- a) Flexible aluminium tubes internally lacquered, fitted with a polypropylene screw cap. 25, 27.5 or 55g tubes are contained in boxboard cartons, together with a polyethylene screw-on applicator nozzle.
  
- b) Aluminium laminate tube consisting of 150µm Polyethylene /5µm polyacrylate outer layer, 30µm aluminium and an inner layer of 30µm polyacrylate / 60µm polyethylene, fitted with a HD polyethylene shoulder, an aluminium/surlyn tamper evident seal, polypropylene cap and a loose polyethylene screw-on applicator nozzle.

#### **6.6 Special precautions for disposal**

Not applicable.

### **7 MARKETING AUTHORISATION HOLDER**

Bayer plc  
400 South Oak Way  
Reading  
RG2 6AD

### **8 MARKETING AUTHORISATION NUMBER(S)**

PL 00010/0265

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

26/11/1990 / 19/03/2001

### **10 DATE OF REVISION OF THE TEXT**

22/03/2018