SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Germoloids Suppositories

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Zinc oxide	Ph. Eur.	283.5 mg
Lidocaine hydrochloride	Ph. Eur.	13.2 mg

3 PHARMACEUTICAL FORM

Suppository for 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 12 years and over:

One suppository to be inserted into the rectum on retiring at night and in the morning, preferably after bowel movement.

If necessary Germoloids Suppositories may be used at any time during the day with a minimum 3 - 4 hours between suppositories.

Do not use more than 4 suppositories in any 24-hour period.

Children under 12 years:

Only as directed by a doctor.

The elderly:

The normal adult dose may be used.

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 suppositories

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 stated.

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.

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 rectal administration of large quantities (up to 30-fold greater doses).

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

Lidocaine hydrochloride has a local anaesthetic action.

The suppository base has lubricant and 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

Hard fat
Methyl salicylate
Glyceryl tristearate

6.2 Incompatibilities

None known

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Germoloids Suppositories come filled in a pre-formed, PVC/polyethylene laminate mould approximately 3cm in length, in strips of six suppositories.

Strips of suppositories are packed in boxboard cartons. Six suppositories per strip, two or four strips per carton, to give pack sizes of 12 or 24 suppositories.

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 00010/0264

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

01/09/1982 / 13/08/2001

10 DATE OF REVISION OF THE TEXT

22/03/2018