## 1. NAME OF THE MEDICINAL PRODUCT

Anusol Suppositories

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each suppository contains:

Bismuth Subgallate 59,0 mg

Bismuth Oxide 24,0 mg

Zinc Oxide 296,0 mg

For a full list of excipients, see section 6.1

## 3. PHARMACEUTICAL FORM

Suppositories.

White to off-white, bullet-shaped suppositories with a characteristic balsamic odour.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Anusol Suppositories soothe the pain and irritation of haemorrhoids (piles), and other related anorectal conditions in adults.

### 4.2 Posology and method of administration

Not to be taken orally.

The area around the anal opening should be cleansed with soap and warm water, then dried carefully by patting (not rubbing) with soft toilet tissue or cotton wool before medication is used.

**Adults:**

Remove plastic cover and insert one suppository in the morning, one at bedtime and one after every evacuation or as directed by the physician.

1. Tear along the perforation to remove one suppository from the strip (see figure 1 below).
2. Grasp the two halves of the plastic cover firmly, holding between the thumb and forefinger of each hand (as indicated in figure 2 below). Gently pull apart to fully expose the suppository.
3. Remove the suppository, and insert as deeply into the anus as possible.

The suppositories are specially shaped for easy insertion into the anus. You may find insertion of the suppositories easier if you place one foot on a chair or lie on your side with one leg drawn up as high as possible under the chin.

Figure 1

Figure 2

**Children:** Not recommended.

**Paediatric population:** Not recommended.

**4.3 Contraindications**

Serious rectal pathology. Haemorrhoids and other inflammatory conditions of the rectum are sometimes of a serious nature. In cases of rectal bleeding, or persistence of the condition, consult your doctor.

Known hypersensitivity to any of the ingredients.

**4.4 Special warnings and precautions for use**

As with all bismuth-containing preparations, neurotoxicity may occur with prolonged or excessive use.

### 4.5 Interaction with other medicines and other forms of interaction

No interaction data related to Anusol Suppositories.

### 4.6 Fertility, pregnancy and lactation

The safety of Anusol Suppositories in pregnancy and lactation has not been established.

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

Anusol Suppositories have no or negligible influence on the ability to drive or use machines.

### 4.8 Undesirable effects

Hypersensitivity reactions may occur. Use should be discontinued if redness, irritation, swelling or pain persists or increases.

### 4.9 Overdose

In overdose, side effects can be precipitated and/or be of increased severity (see section 4.8) Treatment is symptomatic and supportive.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

*Pharmacological classification*

Category A 11.8 Suppositories and anal ointments.

*Pharmacological action*

Anusol Suppositories lubricate and soothe, and help to reduce the oedema and pain of irritated anorectal membranes.

### 5.2 Pharmacokinetic properties

Data for this was not available at time of registration.

### 5.3.Preclinical safety data

N/A

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Balsam peru

Miglyol 812 (fractionated coconut oil)

Hard fat (Suppocire BS2 pastilles)

Kaolin light

Titanium dioxide CI 77891

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

36 months

### 6.4 Special precautions for storage

Keep in a cool (at or below 30 °C), dry place.

### 6.5 Nature and contents of container

A pack containing two PVC blisters of 6 suppositories each (12 suppositories).

### 6.6 Special precautions for disposal and other handling

No special requirements.

## 7 HOLDER OF CERTIFICATE OF REGISTRATION

MDI Healthcare CC

374 Anderson Street

Menlo Park, 0081

South Africa

Customer service: wecare@acdoco.co.za

## 8. MARKETING AUTHORISATION HOLDER

FDA/SD.245-081317

## 8 DATE OF FIRST AUTHORISATION

8/20/2024

## 9 DATE OF REVISION OF THE TEXT

8/2025