

## **SUMMARY OF PRODUCT CHARACTERISTICS**

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

Anusol Ointment

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

Each 100g ointment contains:

Zinc Oxide	10.75 g
Bismuth Subgallate	2.25 g
Balsam Peru	1.875 g
Bismuth Oxide	0.875 g

For full list of excipients, see section 6.1

### **3 PHARMACEUTICAL FORM**

A light buff coloured ointment.

### **4 CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

Symptomatic relief of uncomplicated internal and external haemorrhoids, pruritus ani, proctitis and fissures. Also indicated post operatively in ano-rectal surgical procedures and after incision of thrombosed or sclerosed ano-rectal veins.

Anusol Ointment provides antiseptic, astringent and emollient properties which help to relieve discomfort associated with minor ano-rectal conditions.

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

Topical.

**Adults and Elderly (over 65 years):** Apply to the affected area at night, in the morning and after each evacuation until the condition is controlled. Thoroughly cleanse the affected area, dry and apply ointment. Anusol Ointment should be applied on a gauze dressing. For internal conditions use rectal nozzle provided and clean it after each use. Not to be taken orally.

**Children:** Not recommended

#### **4.3 Contraindications**

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1

#### **4.4 Special warnings and precautions for use**

Patients with rectal bleeding or blood in the stool should talk to their doctor before using this product as these conditions may be the symptom of a more serious underlying disorder.

If symptoms persist or worsen, patients should be instructed to stop use and consult a physician.

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

None known.

#### **4.6 Fertility, Pregnancy and lactation**

Whilst formal studies on the effect of this product during pregnancy have not been conducted, there is no epidemiological evidence of adverse effects either to the pregnant mother or foetus.

This product should not be used during pregnancy and lactation unless the potential benefit of treatment to the mother outweighs the possible risk to the developing foetus or nursing infant.

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

None known

#### 4.8 Undesirable effects

No Adverse Drug Reactions (ADRs) have been identified from the analysis of post-marketing data for fixed combinations of Balsam Peru, bismuth oxide and zinc oxide.

ADRs identified during Post-Marketing experience with **Zinc Oxide** (topical use) are included in the Table below. The frequencies are provided according to the following convention

Very common  $\geq 1/10$

Common  $\geq 1/100$  and  $< 1/10$

Uncommon  $\geq 1/1,000$  and  $< 1/100$

Rare  $\geq 1/10,000$  and  $< 1/1,000$

Very rare  $< 1/10,000$

Not known (cannot be estimated from the available data)

ADRs are presented by frequency category based on 1) incidence in adequately designed clinical trials or epidemiology studies, if available, or 2) when incidence cannot be estimated, frequency category is listed as 'Not known'.

<b>System Organ Class (SOC)</b>	<b>Frequency</b>	<b>Adverse Drug Reaction (Preferred Term)</b>
<b>Immune System Disorders</b>	Rare	Hypersensitivity
<b>General Disorders and Administration site conditions</b>	Not known	Application site reactions (including Burn, erythema, Exfoliation, Irritation, Pain, Pruritus, Rash and Urticaria)

Other adverse reactions include: Skin sensitisation reactions and systemic contact dermatitis, attributed directly to **Balsam Peru** have been reported in published literature

### **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**

No overdose related adverse drug reactions have been identified from the post-marketing data analysis of Balsam Peru, bismuth oxide, and zinc oxide.

The ingestion of topical zinc oxide can potentiate gastrointestinal symptoms like stomach pain, nausea, vomiting, and diarrhoea.

Symptoms of acute oral overdose of bismuth-containing preparations may include nausea, vomiting, renal failure and rarely liver damage. Encephalopathy and discolouration of mucous membranes may occur with chronic overdose.

No cases of Balsam Peru overdose have been identified in the medical literature.

Treatment of a large acute overdose should include gastric lavage, purgation with magnesium sulphate and complete bed rest. If necessary, apply oxygen and give general supportive measures.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

*Pharmacotherapeutic group:* Other agents for treatment of haemorrhoids and anal fissures for topical use, *ATC code:* C05AX

Anusol Ointment provides antiseptic, astringent and emollient properties which help to relieve discomfort associated with minor ano-rectal conditions.

Bismuth Oxide is weakly astringent with supposed antiseptic properties and has a protective action on mucous membranes and raw surfaces.

Zinc Oxide is an astringent and mild antiseptic and probably owes its actions to the ability of the zinc ion to precipitate protein but other mechanisms may be involved. Zinc Oxide is also used to absorb skin moisture and decrease friction and discourage growth of certain bacteria.

Balsam Peru has a very mild antiseptic action by virtue of its content of cinnamic and benzoic acids. It is believed to promote the growth of epithelial cells.

## **5.2 Pharmacokinetic properties**

The active ingredients exert their therapeutic effect without being absorbed into the systemic circulation. These observations are supported by evidence from various studies and reviews.

## **5.3 Preclinical safety data**

The active ingredients of Anusol are well known constituents of medicinal products and their safety profile is well documented.

# **6 PHARMACEUTICAL PARTICULARS**

## **6.1 List of excipients**

Anusol Ointment contains the following excipients:-

Magnesium stearate  
Cocoa butter  
Lanolin anhydrous  
Castor oil  
Kaolin light  
Petroleum Jelly White

## **6.2 Incompatibilities**

None known.

## **6.3 Shelf life**

Not less than 3 years when stored in the original packing.

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

Do not store above 25°C.

For storage conditions after first opening of the medicinal product, see section 6.3

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

Externally printed and internally lacquered 25 g aluminium tube with plastic cap. A plastic nozzle with cap is also provided for internal application.

Not all pack sizes may be marketed

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

No special requirements

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

### **7 MARKETING AUTHORISATION HOLDER**

Church & Dwight UK Limited  
Premier House, Shearway Business Park  
Pent Road,  
Folkestone, Kent,  
CT19 4RJ  
United Kingdom

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

PL 00203/0232

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

14<sup>th</sup> March 1997

**10 DATE OF REVISION OF THE TEXT**

30/06/2017