SUMMARY OF PRODUCT CHARACTERISTICS

1  NAME OF THE MEDICINAL PRODUCT

ANUSOL cream

2  QUALITATIVE AND QUANTITATIVE COMPOSITION

ANUSOL cream contains -

- Zinc oxide Ph Eur 10.75 g
- Bismuth oxide 2.14 g
- Balsam Peru Ph Eur 1.8 g

For full list of excipients, see section 6.1

3  PHARMACEUTICAL FORM

A buff coloured cream

4  CLINICAL PARTICULARS

4.1  Therapeutic indications

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

ANUSOL cream also provides lubricating properties for use with suppositories.

Indicated for the 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.
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 cream. ANUSOL cream is prepared in a vanishing cream base and may be gently smoothed on to the affected area without the need to apply 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 human pregnancy have not been conducted, there is no epidemiological evidence of adverse effect, 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’.

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

4.9 Overdose

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 cream provides antiseptic, astringent and emollient properties which help to relieve discomfort associated with minor ano-rectal conditions. It also provides lubricating properties for use with suppositories.

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 profiles are well documented.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol monostearate Ph Eur
Liquid paraffin Ph Eur
Propylene glycol Ph Eur
Polysorbate 60 Ph Eur
Sorbitan stearate BP
Titanium dioxide Ph Eur
Methyl p-hydroxybenzoate Ph Eur
Propyl p-hydroxybenzoate Ph Eur
Purified water Ph Eur

6.2 Incompatibilities

None known.

6.3 Shelf life

3 years when stored in the original packaging.

6.4 Special precautions for storage

Store at a temperature not exceeding 25°C.
For storage conditions after first opening of the medicinal product, see section 6.3

6.5 **Nature and contents of container**

Pack size 23g, 30g or 43g, externally printed and internally lacquered 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 00203/0231
9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORIZATION

15 September 1997

10 DATE OF REVISION OF THE TEXT

30/06/2017