

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Anusol Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 g of Anusol Cream contains:

Zinc oxide	10.75 g
Bismuth oxide	2.14 g
Peru balsam	1.8 g (contains benzyl alcohol, benzyl benzoate and benzyl cinnamate)

Excipients with known effect:

Propylene glycol

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Cream

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 is 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.

Anusol Cream also provides lubricating properties for use with suppositories.

4.2 Posology and method of administration

Posology

Children and adolescents under 18 years of age
Not Recommended.

Adults 18 years and over

Apply to the affected area at night, in the morning and after each evacuation until the condition is controlled.

Elderly

As for adults

Method of administration

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. Remove the nozzle cap. Clean the nozzle after each use.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Not to be taken orally.

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.

This medicine contains 8000 mg propylene glycol in each 100 g. Propylene glycol may cause skin irritation.

Peru balsam may cause skin reactions.

- This medicine contains approximately 126 mg benzyl alcohol in each 100 g. Benzyl alcohol may cause allergic reactions and/or mild local irritation.

- This medicine contains approximately 1350 mg benzyl benzoate in each 100 g. Benzyl benzoate may cause local irritation.
- Benzyl cinnamate may cause allergic reactions.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

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 Peru balsam, 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’.

System Organ Class (SOC)	Frequency	Adverse Drug Reaction (Preferred Term)
Immune System Disorders	Rare	Hypersensitivity
General Disorders and Administration site conditions	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 Peru balsam 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

Mechanism of action

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. Peru balsam 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 Cream are well known constituents of medicinal products and their safety profiles are well documented.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol monostearate
Liquid paraffin
Propylene glycol
Polysorbate 60
Sorbitan stearate
Titanium dioxide
Phenoxyethanol
Chlorphenesin
Glycerol
Water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years when stored in the original packaging.

After first opening, use within 28 days.

6.4 Special precautions for storage

Do not store above 25°C.

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

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8 MARKETING AUTHORISATION NUMBER(S)

PL 00203/0231

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

Date of first authorization: 15 September 1997

10 DATE OF REVISION OF THE TEXT

14/02/2023