SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Anusol Soothing Relief Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 g of ointment contains the following active substances:

Zinc oxide	10.75 g
Bismuth subgallate	2.25 g
Peru balsam	1.875 g (contains benzyl alcohol, benzyl benzoate and benzyl cinnamate)
Benzyl benzoate	1.25 g
Bismuth oxide	0.875 g
Hydrocortisone acetate	0.25 g

Excipient(s) with known effect
Lanolin anhydrous

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Ointment.
A smooth, homogeneous buff coloured ointment with the characteristic odour of Peru balsam

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Anusol Soothing Relief Ointment is indicated in adults for the symptomatic treatment of uncomplicated internal and external haemorrhoids and pruritus ani.

4.2 Posology and method of administration

Posology

Adults 18 years and over
To be applied sparingly to the affected area at night, in the morning and after each evacuation up to a maximum of 4 applications a day.

Use for a maximum period of one week.

Elderly (over 65 years)
As for adults.

Children and adolescents under 18 years
Not recommended.

Method of administration
Thoroughly cleanse the affected area, dry and apply ointment on a gauze dressing. For internal conditions use rectal nozzle provided. Remove the nozzle cap. Clean the nozzle after each use. After each use, gently wipe off excess ointment from the external thread of the tube.

4.3 Contraindications

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

Tubercular, fungal and most viral lesions including herpes simplex, vaccinia and varicella.

Do not use in pregnancy or breastfeeding.

4.4 Special warnings and precautions for use

For topical administration only. 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.

The product should be discontinued and the patient advised to consult a medical practitioner if symptoms do not improve or worsen or if rectal bleeding occurs.

As with all products containing topical steroids, the possibility of systemic absorption should be borne in mind. Prolonged or excessive use may produce systemic corticosteroid effects. Do not use for more than 7 days unless under the direction of a doctor.

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

This medicine contains approximately 2.66 g **benzyl benzoate** in each 100 g. Benzyl benzoate may cause local irritation.

Peru balsam contains **benzyl alcohol** (approximately 131 mg in each 100 g of ointment), **benzyl benzoate** and **benzyl cinnamate**. It may cause allergic reactions, mild local irritation and/or skin reactions.

Excipient with known effect:
Wool fat (lanolin) may cause local skin reactions e.g. contact dermatitis which is a local irritation at the site of use. Wool fat (lanolin) may contain an antioxidant, **butylated hydroxytoluene** (E321), which may cause local skin reactions (e.g. contact dermatitis) or irritation to the eyes and mucous membranes.

4.5 Interaction with other medicinal products and other forms of interaction

Concurrent use with other corticosteroid preparations, either topically or orally may increase the likelihood of systemic effects.

Co-treatment with CYP3A inhibitors, including cobicistat containing products, is expected to increase the risk of systemic effects. The combination should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid side-effects.

4.6 Fertility, pregnancy and lactation

There is inadequate evidence of safety in human pregnancy and there may be a very small risk of cleft palate and intrauterine growth retardation as well as suppression of the neonatal hypothalamic-pituitary-adrenal axis. There is evidence of harmful effects in animals.

Do not use in pregnancy or breastfeeding.

4.7 Effects on ability to drive and use machines

Anusol Soothing Relief Ointment has no or negligible influence on the ability to drive and use machines.

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 ≥1/10
Common ≥1/100 and < 1/10
Uncommon ≥1/1,000 and <1/100
Rare ≥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)
Eye Disorders	Not known	Vision, blurred (see also section 4.4)

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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

No overdose related adverse drug reactions have been identified from the post-marketing data analysis of Peru balsam, benzyl benzoate, bismuth oxide, bismuth subgallate, hydrocortisone acetate and zinc oxide.

If swallowed, fever, nausea, vomiting, stomach cramps and diarrhoea may develop 3-12 hours after ingestion.

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 Peru balsam overdose have been identified in the medical literature.

Hydrocortisone normally does not produce toxic effects in an acute single overdose.

Prolonged use of topical corticosteroids may increase potential for local adverse effects, including steroid atrophy (thinning of the skin), striae (stretch marks), and Telangiectasia (visible blood vessels). Systemic availability after rectal administration is very low; however, excessive administration of corticosteroids may increase the potential for systemic effects, such as hypothalamic-pituitary axis suppression.

Treatment of a large acute overdose should include gastric lavage, purgation with magnesium sulphate and complete bed rest. If necessary oxygen and general supportive measures should be given. Methaemoglobinaemia should be treated by intravenous methylthioninium chloride.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Agents for treatment of haemorrhoids and anal fissures for topical use, ATC code: C05A A01

Mechanism of action

Anusol Soothing Relief Ointment provides antiseptic, astringent, emollient and decongestant properties. In addition hydrocortisone exerts anti-inflammatory actions.

Bismuth oxide, zinc oxide, and bismuth subgallate exert a protective action on mucous membranes and raw surfaces. They are mildly astringent and are reported to have antiseptic properties.

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

Benzyl benzoate is used as a solubilizing agent and has mild antiseptic and preservative properties.

Hydrocortisone acetate has the general properties of hydrocortisone and this anti-inflammatory action is of primary interest of this product.

5.2 Pharmacokinetic properties

Systemic absorption of hydrocortisone acetate from the rectum may occur but estimates of the extent of absorption have been variable and have always been less than 30%. Following absorption it is metabolised in the liver and most body tissues before being excreted in the urine. Biological half-life is approximately 100 minutes and it is 90% bound to plasma protein.

The other active ingredients in this product exert their therapeutic effect without being absorbed into the systemic circulation. These 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.

There are no preclinical data of relevance to the prescriber, which are additional to those already included in other sections of the SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Petroleum jelly white
Calcium hydrogen phosphate
Lanolin anhydrous (may contain butylated hydroxytoluene (E321))
Cocoa butter
Castor oil
Kaolin light
Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C

6.5 Nature and contents of container

Anusol Soothing Relief Ointment is presented in an aluminium tube closed with a wadded plastic cap, containing 15 g of ointment. A plastic nozzle with cap is also provided for internal application.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

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

7 MARKETING AUTHORISATION HOLDER

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United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 00203/0234

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21/11/2013

10 DATE OF REVISION OF THE TEXT

13/06/2025