SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

ANUSOL HC OINTMENT

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100g of ointment contains:

Hydrocortisone acetate	0.25g
Bismuth subgallate	2.25g
Bismuth oxide	0.875g
Balsam Peru	1.875g
Benzyl benzoate	1.25g
Zinc oxide	10.75g

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Ointment.

Buff-coloured ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Anusol-HC Ointment is indicated for the comprehensive symptomatic treatment of internal and external haemorrhoids and pruritus ani.

4.2 Posology and method of administration

Anal application.

ADULTS

Apply ointment to the affected area at night, in the morning and after each evacuation up to a maximum of 4 applications a day. 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. Use for a maximum period of one week.

Not to be taken orally.

ELDERLY (OVER 65 YEARS)

As for adults.

CHILDREN

Not recommended.

4.3 Contraindications

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

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

Do not use in pregnancy or breast-feeding.

4.4 Special warnings and precautions for use

Following symptomatic relief, definitive diagnosis should be established.

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.

As with all products containing topical steroids, the possibility of systemic absorption should be borne in mind.

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

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

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.

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 HPA 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

Not applicable.

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 ≥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 **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

No overdose related adverse drug reactions have been identified from the post-marketing data analysis of Balsam Peru, 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 Balsam Peru 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, give oxygen and general supportive measures. 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

This product provides antiseptic, astringent, emollient and 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.

Balsam Peru has protective properties and 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.

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

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

5.2 Pharmacokinetic properties

It is well known that topically applied corticosteroids can be absorbed percutaneously. This appears to be more likely upon repeated or prolonged use.

The other active ingredients in Anusol HC Ointment 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

Pre-clinical safety data do not add anything of further significance to the prescriber.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium stearate

Cocoa butter
Lanolin anhydrous
Castor oil
Kaolin light
White Petroleum jelly
Calcium hydrogen phosphate

6.2 Incompatibilities

None applicable.

6.3 Shelf life

36 months

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 Aluminium tube with plastic cap containing 15g, 25g or 30g 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

Not applicable.

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 00203/0238

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1 June 2002

10 DATE OF REVISION OF THE TEXT

30/06/2017