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	0.25 g
Benzyl Benzoate	1.25 g
Bismuth Subgallate	2.25 g
Bismuth oxide	0.875 g
Balsam Peru	1.875 g
Zinc Oxide	10.75 g

Excipient:
Wool Fat 8.00 g

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

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

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Anusol HC Ointment is indicated for the symptomatic relief of external and internal haemorrhoids, proctitis, cryptitis, anal fissures, pruritus ani and perianal sinuses. Also indicated post-operatively in ano-rectal surgical procedures.

4.2 Posology and method of administration

Topical.

Adults
Thoroughly cleanse the affected area, dry and apply ointment on a gauze dressing. Apply ointment to the affected area at night, in the morning and after each evacuation. For internal conditions use rectal nozzle provided and clean it after each use. Do not use for longer than 7 days, unless on the advice of a doctor.

Not to be taken orally.

Elderly (over 65 years)
As for adults.

Children
Not recommended.

4.3 Contraindications

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

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

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.

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 with suppression of adrenocortical function and toxicity. Use for periods longer than seven days is not recommended unless under the direction of a doctor.

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

Continuous application without interruption will result in local atrophy of the skin, striae and superficial vascular dilatation.

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 interactions

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

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

There are no adequate and well-controlled clinical studies of fixed combinations of balsam peru, benzyl benzoate, bismuth oxide, bismuth subgallate, zinc oxide and hydrocortisone acetate in pregnant or breast-feeding women. 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.

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 listed below by System Organ Class (SOC).

The frequencies are defined in accordance with current guidance, as:

Very common ³1/10
Common ³1/100 and <1/10
Uncommon ³1/1,000 and <1/100
Rare ³1/10,000 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)

*Transient ADR especially if the anoderm is not intact.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971 ; Fax: +353 1 6762517 . Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

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

The ingestion of topical zinc oxide can potentiate gastrointestinal symptoms.

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.

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

Hydrocortisone does not normally produce toxic effects inan 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 overdosage 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

Anusol HC Ointment provides antiseptic astringent, emollient and vascular decongestant properties. In addition, hydrocortisone exerts an anti-inflammatory effect.

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 solubilising 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium stearate
Theobroma Oil
Wool fat (Lanolin anhydrous)
Castor oil, virgin
Kaolin light
White Soft Paraffin
Calcium hydrogen phosphate

6.2 Incompatibilities

None 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

External printed aluminium tube, with plastic screw cap, accompanied by a plastic applicator nozzle.
Pack size: 15g, 25g, 30g

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

SOFIBEL
110 – 114 rue Victor Hugo
92686 Levallois Perret Cedex
France

8 MARKETING AUTHORISATION NUMBER

PA22647/002/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30 March 1990

Date of last renewal: 30 March 2010

10 DATE OF REVISION OF THE TEXT

February 2019