Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Anusol Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:
Bismuth Oxide 0.875 g
Peru balsam 1.875 g (contains benzyl alcohol, benzyl benzoate and benzyl cinnamate)
Zinc Oxide 10.75 g
Bismuth Subgallate 2.25 g

Excipients with known effect:
Wool fat (E913) (may contain butylated hydroxytoluene (E321))
Castor oil
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Ointment
A buff coloured ointment having the characteristic odour of Peru balsam.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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

Indicated for the symptomatic relief of uncomplicated internal and external haemorrhoids, pruritus ani, proctitis and fissures as diagnosed by a doctor. Also indicated post-operatively in ano-rectal surgical procedures and after incision of thrombosed sclerosed ano-rectal veins as advised by a doctor.

4.2 Posology and method of administration

Posology:
Adults 18 years and over
Apply to the affected area at night, in the morning and after each evacuation until the condition is controlled.

Children and adolescents under 18 years of age:
Use only under medical advice.

The Elderly:
As for adults.

Method of administration

Thoroughly cleanse the affected area, dry and apply ointment. Anusol Ointment should be applied on a gauze dressing. For internal conditions use rectal nozzle provided and clean it after each use.

Anusol ointment should be used cautiously to avoid large amounts of disposal via wastewater or household waste.

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

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 stop use and consult their doctor.

Peru balsam may cause skin reactions.

- This medicine contains approximately 1406 mg benzyl benzoate in each 100g. Benzyl benzoate may cause local irritation. It may cause non-immunologic immediate contact reactions by a possible cholinergic mechanism.

- This medicine contains approximately 131 mg benzyl alcohol in each 100g. Benzyl alcohol may cause allergic reactions and/or mild local irritation. In addition to allergic reactions in sensitised patients, non-sensitised patients may become sensitised.

- Benzyl cinnamate may cause allergic reactions. In addition to allergic reactions in sensitised patients, non-sensitised patients may become sensitised.

Castor oil may cause skin reactions.

Wool fat may cause local skin reactions (e.g. contact dermatitis). Wool fat may contain an antioxidant, butylated hydroxytoluene, which may cause local skin reactions (e.g. contact dermatitis) or irritation to the mucous membranes.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

There are no adequate and well-controlled clinical studies of fixed combinations of Peru balsam, bismuth oxide, bismuth subgallate and zinc oxide in pregnant or breast-feeding women. 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 listed below by System Organ Class (SOC). The frequencies are defined in accordance with current guidance, as:

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)

System Organ Class (SOC)	Frequency	Adverse Drug Reaction (Preferred Term)
Immune System Disorders	Rare	Hypersensitivity (such as rash)
General Disorders and Administration site conditions	Not known	Application site reactions (including Burn*, Erythema, Exfoliation, Irritation, Pain, Pruritus, Rash and Urticaria)

*Especially if the anoderm is not intact.

ADRs will usually stop when use of the ointment is stopped.

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 HPRA Pharmacovigilance, Website: www.hpra.ie.

4.9 Overdose

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

The ingestion of topical zinc oxide can potentiate gastrointestinal symptoms like stomach pain, nausea, vomiting, and diarrhoea.

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.

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; zinc preparations, ATC code: C05AX04

Mechanism of action
Anusol Ointment provides antiseptic, astringent and emollient properties which help to relieve discomfort associated with minor ano-rectal conditions.

Bismuth oxide is a weak 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

No pharmacokinetic data available because of minimal absorption of the ingredients.

Absorption: 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. **Distribution:** Not applicable.
Metabolism and Elimination: Not applicable.

5.3 Preclinical safety data

Mutagenicity, Carcinogenicity and Teratogenicity: As the active ingredients exert their therapeutic effect without being absorbed into the systemic system it is not believed that mutagenicity, carcinogenicity or teratogenicity present significant risks.

Fertility: As the active ingredients exert their therapeutic effect without being absorbed into the systemic system it is not believed that there is a risk to fertility.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium stearate
Cocoa butter
Wool fat (may contain butylated hydroxytoluene)
Castor oil
Kaolin light
Paraffin white soft

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25^{o}C.

6.5 Nature and contents of container

25g pack. Anusol Ointment is presented in a aluminium tube closed with a white high density polyethylene cap. The tube is accompanied with a plastic applicator nozzle.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PA22647/001/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 03 April 1990

Date of last renewal: 03 April 2010

10 DATE OF REVISION OF THE TEXT

December 2021