Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

AnuSol Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 g of AnuSol cream contains:

Active substances:
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 8.00 g

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream
A smooth, homogeneous, buff coloured cream with the characteristic odour of Peru balsam.

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 also provides lubricating properties for use with suppositories.

AnuSol cream is 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:
Not recommended, except under medical advice.

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 onto the affected area without the need to apply a gauze dressing. For internal conditions use rectal nozzle provided and clean it after each use.

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.

Excipients:

This medicine contains 8.0 g propylene glycol in each 100 g which is equivalent to 80 mg/g.

This medicine contains Peru balsam, which contains benzyl alcohol, benzyl benzoate and benzyl cinnamate. Peru balsam may cause allergic reactions and/or mild local irritation and/or skin 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

There are no adequate and well-controlled clinical studies of fixed combinations of Peru balsam, bismuth oxide, 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)

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 (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 cream 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, 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, 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, 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

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.

Pharmacokinetics in Renal Impairment: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

Glycerol monostearate
Liquid paraffin
Propylene glycol
Polysorbate 60
Sorbitan stearate
Titanium dioxide (E171)
Phenoxyethanol
Chlorphenesin
Glycerol
Water

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

23 g and 43 g pack. AnuSol cream is presented in a collapsible tube made from lacquered aluminium with a white polyethylene cap. The tube is accompanied by a plastic applicator nozzle.

Not all pack sizes may be marketed

6.6 Special precautions for disposal

No special requirements.

Any unused medicinal product or waste material should bedisposed 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

PA22647/001/001

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

May 2024