Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Anusol Suppositories

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Suppository contains:

Bismuth oxide anhydrous	24 mg
Zinc Oxide	296 mg
Balsam Peru	49 mg
Bismuth Subgallate	59 mg

For a full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Suppository
White or off white suppositories having the characteristic odour of Balsam Peru.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Indicated for the symptomatic relief of uncomplicated internal haemorrhoids, or post-operatively after ano-rectal procedures using surgical or sclerosing techniques.

4.2 Posology and method of administration

Adults and children 12 years and over: Remove wrapper and insert into the anus at night, in the morning and after each evacuation. Not to be taken orally.

Children under 12 years: Not recommended, except under medical advice.

The Elderly: As for adults.

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

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.

4.5 Interaction with other medicinal products and other forms of interactions

None known.

4.6 Fertility, pregnancy and lactation

There are no adequate and well-controlled clinical studies of fixed combinations of balsam peru, 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

No special comment, Anusol Suppositories are unlikely to produce an effect.

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 (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 suppositories is stopped.

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 authorisationof the medicinal product is important. It allows continued monitoring of thebenefit/risk balance of the medicinal product. Healthcare professionals areasked 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, 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 Balsam Peru 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

Anusol Suppositories provide 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.

Balsam Peru 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 is 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.

Pharmacokinetics in the Elderly: As for adults.

5.3 Preclinical safety data

Mutagenicity, Carcinogenicity and Teratogenicity: As theactive ingredients exert their therapeutic effect without being absorbed intothe systemic system it is not believed that mutagenicity, carcinogenicity orteratogenicity present significant risks.

Fertility: As the active ingredients exert theirtherapeutic effect without being absorbed into the systemic system it is notbelieved that there is a risk to fertility.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hard Fat (Suppocire BS2 Pastilles)
Kaolin Light
Titanium Dioxide (E171)
Miglyol 812

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

12 or 24 Anusol Suppositories are presented in a printed strip pack, consisting of PVC/polyethylene laminated film.

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

PA22647/001/003

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