

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) OF
ANUDOL SUPPOSITORY

1. NAME OF THE MEDICINAL PRODUCT

ANUDOL SUPPOSITORY

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Suppository contains:

Zinc Oxide 296mg

Bismuth Subgallate 59mg

Balsam Peru 49mg

Bismuth Oxide 24mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

White or off-white glossy, bullet shaped suppository

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of internal piles and other related conditions. It helps to relieve the swelling, itching and irritations caused by internal piles (haemorrhoids) and other related conditions, such as anal itching.

4.2 Posology and method of administration

Posology

Anal insertion

Adults, Elderly and Children over 18 years:

Remove wrapper and insert one suppository into the back passage (anus) far enough so that it doesn't slip out, at night, in the morning and after each bowel movement. Not to be taken orally.

Pediatric population

Not recommended for children under 18 years.

Method of administration

ANUDOL Suppositories should be inserted into the anus.

- Wash anal area and dry gently with a soft towel before using this medicine.
- Remove plastic cover from suppository before use.
- Wash your hands before and after using ANUDOL.
- The suppository will melt after insertion.

4.3 Contraindications

Do not use ANUDOL for children under 18 years old and if you experience hypersensitivity to the active substance or to any of the excipients of this medicine (as listed in section 6.1).

4.4 Special warnings and precautions for use

Pregnancy and Lactation: If you are pregnant or breast-feeding, only use this medicine on the advice of your doctor.

Rectal bleeding or blood in the stool: Talk to your doctor or pharmacist if you have rectal bleeding or blood in the stool or if you are in doubt whether any bleeding you have experienced is caused by piles.

If symptoms persist or worsen, patients should stop use and consult their doctor.

4.5 Interaction with other medicinal products and other forms of interaction

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

None known

4.8 Undesirable effects

Like all medicines, ANUDOL can cause side effects. These however, are quite rare. If hypersensitivity reactions (such as rash) is experienced, stop using the medicine and talk to your doctor. Other effects which may occur includes; burning, redness. Irritation, itching, or pain at

the site of application. This does not usually last a long time, so if this lasts longer than a few days, tell your doctor.

If you experience any side effects not included above, talk to your doctor or pharmacist.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization 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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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 discoloration 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

Pharmacotherapeutic group: Other agents for treatment of haemorrhoids and anal fissures for topical use, *ATC code:* C05AX

ANUDOL 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 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

Hard Fat Suppocire

Kaolin Light

Titanium Dioxide

Miglyol 812

6.2 INCOMPATIBILITIES

Not applicable

6.3 Shelf life

12 months.

6.4 Special precautions for storage

ANUDOL should be stored in a cool dry place, not above 30⁰C. Keep all medicines out of sight and reach of children.

6.5 Nature and contents of container

Individual Printed pack of 12 Printed strips of white opaque PVC/PE laminated shells of 296mg Zinc Oxide ANUDOL Suppositories.

6.6 Special precautions for disposal and other handling

No special requirements.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Daily-Need Industries Limited
Plots 9 &10 Daily-Need lane,off Ladipo street,Matori-Lagos State
www.dailyneedgroup.com,
info@dailyneedgroup.com

8. MARKETING AUTHORISATION NUMBER(S)

A11-1075

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION

NA

10. DATE OF REVISION OF THE TEXT

NA

COMPANY CONTACT DETAILS

Daily-Need Industries Limited

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