

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Antipeol
St James' Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Constituents: (% w/w)

Zinc Oxide 20.0

Ichthammol (1 in 3 dilution) 2.8

Salicylic Acid 0.1

3 PHARMACEUTICAL FORM

Ointment

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Soothing ointment for relief of minor skin problems

4.2 Posology and method of administration

For general use, smear the ointment around the affected area.

4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients

4 CLINICAL PARTICULARS

4.4 Special warnings and precautions for use

Keep out of the sight and reach of children.

Instruct patients not to smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

4.5 Interaction with other medicinal products and other forms of interaction

There are no known interactions.

4.6 Fertility, pregnancy and lactation

There is no data on use during pregnancy and lactation

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

Salicylic Acid, Ichthammol and Urea can cause irritation to the skin. Wool fat (lanolin) may cause local skin reactions (e.g. contact dermatitis)

This product should be discontinued should this occur.

4.9 Overdose

Not applicable - for topical use

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: D02AB

Zinc Oxide is a soothing and protective agent. Ichthammol and Salicylic Acid have bacteriostatic properties.

5.2 Pharmacokinetic properties

No data is available concerning the pharmacokinetic properties.

5.3 Preclinical safety data

Zinc Oxide, Ichthammol, Salicylic Acid and Urea are widely used in topical skin care products. Pharmacopoeial standard constituents are used. There has been no specific testing of these constituents and no preclinical data are available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid Paraffin

Yellow Soft Paraffin

Wool Fat

Urea

Lavender Oil

6.2 Incompatibilities

None known

6.3 Shelf life

3 years from date of manufacture

6.4 Special precautions for storage

Store in a cool place

6.5 Nature and contents of container

Not all pack sizes may be marketed.

Compressible aluminium tubes containing 18, 37 or 93g of product.

6.6 Special precautions for disposal

No special instructions are necessary.

7 MARKETING AUTHORISATION HOLDER

Aspar Pharmaceuticals Ltd
Albany House, Acrewood way,
St Albans, AL4 0JY,
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 08977/0048

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

08/06/1988

10 DATE OF REVISION OF THE TEXT

09/01/2024