Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product

Scabees Application 25% w/v
(Benzyl Benzoate 25% w/v Topical Emulsion)

Each 100 ml of product contains 25 g of Benzyl Benzoate.

Pharmaceutical form: Topical emulsion.

2. Qualitative and quantitative composition

Name of Ingredient	Quantity (%w/v)
Benzyl benzoate	25% w/v of Benzyl benzoate

Excipients of known effect

Name of Excipient	Quantity (%w/v)
Emulsifying wax BP	2.300% w/v
Benzyl alcohol BP	0.500% v/v
Chlorocresol BP	0.100% w/v
Myacide (bronopol)	0.020% w/v

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Topical emulsion.

Product description: Clean, white, viscous emulsion free from visible evidence of contamination, with characteristic odour.

4. Clinical particulars

4.1 Therapeutic indications

Benzyl benzoate is an acaricide used in the treatment of scabies and pediculosis.

4.2 Posology and method of administration

Posology

(a) Scabies

Apply thoroughly to the entire body at night from the soles of the feet, omitting the head and neck, for 2 consecutive nights. The lotion is left in place for 8-12 hours on each night and may be followed by a repeated application at night 7 days later. In the case of lesions affecting the head, face and/or neck, it may be necessary to consult a healthcare professional before using this product. Thorough bathing with complete changes of clothing and bedding should follow each application. All contacting clothes and bedding should be washed and/or cleaned.

(b) Pediculosis

Apply to the affected area and allow to remain on for 24 hours, then wash thoroughly. In severe cases 2 or 3 treatments may be repeated after 7 and 14 days. Thorough bathing with complete changes of clothing should follow each application. All contacting clothing and bedding should be washed and/or cleaned.

Method of administration
For topical application on skin.

4.3 Contraindications
Use in persons hypersensitive to the active ingredient.

4.4 Special warnings and precautions for use
Local erythema and irritation may occur.

4.5 Interaction with other medicinal products and other forms of interaction
None reported.

4.6 Fertility, pregnancy and lactation
Although no studies on the effects on human pregnancy or lactation have been carried out, the drug is for topical use and is unlikely to represent a hazard to the pregnant or lactating patient.

4.7 Effects on ability to drive and use machines
None known.

4.8 Undesirable effects
Benzyl benzoate is irritant to the eyes and mucous membranes and may be irritant to the skin. Hypersensitivity reactions have been reported. When ingested, benzyl benzoate may cause stimulation of the CNS and convulsions. Systemic symptoms have been reported following excessive topical use.

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose
Treatment of poisoning involves aspiration and lavage and appropriate symptomatic measures.

5. Pharmacological properties

5.1 Pharmacodynamic properties
Therapeutic class: Scabicides and pediculicides.
ATC code: P03AX01.

Benzyl benzoate is an acaricide used in the treatment of scabies and pediculosis.

5.2 Pharmacokinetic properties

Absorbed benzyl benzoate is rapidly bio-transformed to hippuric acid, which is excreted in the urine.

5.3 Preclinical safety data

No further information available.

6. Pharmaceutical particulars

6.1 List of excipients

Emulsifying wax BP (anionic)
Benzyl alcohol BP
Chlorocresol BP
Myacide (bronopol)
Meglumine

6.2 Incompatibilities

None known.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not store above 25°C. Protect from light and moisture.

6.5 Nature and contents of container

Aluminium collapsible tube.
Available in pack sizes of 100 ml, 1 Litre and 5 Litres.

6.6 Special precautions for disposal and other handling

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

7. Marketing authorisation holder

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8. Marketing authorisation number

7429

9. Date of first authorisation/renewal of the authorisation

2024 May 25

10. Date of revision of the text

25th August, 2026