SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

SICAZYL (Benzyl Benzoate Application BP 25 %w/v)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Benzyl Benzoate BP……25%w/v

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cutaneous emulsion
White Coloured lotion.

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

Topical use, Cutaneous use.

(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.

Child and Infant Dosage Instructions

Benzyl Benzoate may be diluted with an equal quantity of water for older children and with three parts of water for infants.

4.3 Contraindications

Use in persons hypersensitive to the active ingredients or allergy to any ingredient.

4.4 Special warnings and precautions for use

Avoid contact with eyes and face.
Local erythema and irritation may occur.
Use can be complicated by allergic contact dermatitis

4.5 Interaction with other medicinal products and other forms of interaction

None reported.

4.6 Fertility, pregnancy and lactation

Ask your doctor or pharmacist for advice before taking any medicine.
It should not be used during pregnancy or in lactating women, infants, or children <2 years of age.

4.7 Effects on ability to drive and use machines

Presumed to be safe and unlikely to produce an effect.

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
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 the Yellow Card Scheme prepaid post, online at https://primaryreporting.who-umc.org/ET or via toll free call 8482 to Ethiopian food and drug authority (EFDA).

4.9 Overdose

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

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

P03AX01 Other ectoparasiticides, incl. Scabicides

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 and purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store below 30°C in a tightly closed container.Protect from light

Keep out of the reach of children.

6.5 Nature and contents of container

100 ml Amber glass bottle with measuring cup packed in monocarton with leaflet.

6.6 Special precautions for disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

Registration No; 05056/07134/REN/2019

9. DATE OF FIRST AUTHORISATION

09/03/2020

10. DATE OF REVISION OF THE TEXT

July 2023