Summary of Product Characteristics
ZASCAB SOLUTION
(Benzyl Benzoate 25% w/v Solution)

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1. Name of the medicinal product
ZASCAB SOLUTION (Benzyl Benzoate 25% w/v Solution)

2. Qualitative and quantitative composition
Each 1.0 ml of solution contains 250 mg (25% w/v) benzyl benzoate.

Excipients with known effect:
Cetostearyl alcohol.
Sodium lauryl sulphate (E487).
For the full list of excipients, see section 6.1.

3. Pharmaceutical form
Cutaneous solution.
White coloured, homogenous, non-gritty solution free from visible evidence of contamination.

4. Clinical particulars

4.1 Therapeutic indications
Benzyl benzoate is an acaricide indicated for the treatment of scabies and pediculosis.

4.2 Posology and method of administration

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 solution 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, application in this region must be made under medical supervision only and requires consultation with a healthcare professional. Thorough bathing with complete changes of clothing and bedding should follow each application. All contacting clothes and bedding should be washed and/or cleaned.

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.

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

Method of administration

Topical (cutaneous) use only.

4.3 Contraindications

Benzyl benzoate is contraindicated in:

- Persons with known hypersensitivity to benzyl benzoate, benzoic acid, benzyl alcohol or any of the excipients listed in section 6.1.
- Children under 2 years of age due to the risk of systemic absorption and CNS toxicity.

4.4 Special warnings and precautions for use

Benzyl benzoate should not come into contact with the eyes, mucous membranes or highly irritated or broken skin. If accidental contact occurs, rinse thoroughly with water.

Antiscabiosum 25% should be applied with particular caution in persons with a history of epileptic seizure, as seizure has been repeatedly triggered by the application of benzyl benzoate emulsion in at least one reported case.

The active substance benzyl benzoate is not phototoxic itself. Under the effect of sunlight, however, phototoxic substances may form. Exposure to intense sunlight is therefore recommended to be avoided during treatment.

Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis).

Sodium lauryl sulphate (E487) may cause local skin reactions such as stinging or burning sensation, or may increase skin reactions caused by other products when applied on the same area. Sensitivity to sodium lauryl sulphate can vary according to body site, age, patient population and other factors such as hydration level, skin colour and disease. Patients with decreased skin barrier function, such as those with atopic dermatitis, are more sensitive to the irritant properties of sodium lauryl sulphate.

4.5 Interaction with other medicinal products and other forms of interaction

No interactions are known. To exclude interactions, ZASCAB SOLUTION should not be used concurrently with other externally applied anti-scabies agents.

4.6 Fertility, pregnancy and lactation

Pregnancy

Insufficient data are available from animal studies with benzyl benzoate. No adequate clinical data are available on the use of benzyl benzoate in pregnancy. Although the drug is for topical use, benzyl benzoate should only be used during pregnancy if the indication is compelling and no safer alternative exists.

Breast-feeding

There are no data on whether benzyl benzoate passes into human breast milk. Due to this uncertainty, ZASCAB SOLUTION is not recommended during breast-feeding.

Fertility

No data are available on the effects of benzyl benzoate on human fertility.

4.7 Effects on ability to drive and use machines

ZASCAB SOLUTION has no known effect on the ability to drive and use machines.

4.8 Undesirable effects

Adverse drug reactions are classified by system organ class using the following frequency conventions:

Very common: ≥1/10; Common: ≥1/100 to <1/10; Uncommon: ≥1/1,000 to <1/100; Rare: ≥1/10,000 to <1/1,000; Very rare: <1/10,000; Not known: cannot be estimated from the available data.

System Organ Class	Frequency	Adverse reaction
Nervous system disorders	Not known	Seizure (in children — see section 4.4)
Skin and subcutaneous tissue disorders	Rare	Skin and mucous membrane irritation, continued pruritus (post-scabies eczema), contact dermatitis
	Not known	Hypersensitivity reactions (including urticaria, angioedema, malaise)
Eye disorders	Not known	Eye irritation (if accidental contact occurs)

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

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation 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 to the National Regulatory Authority.

4.9 Overdose

No known cases of intoxication after topical use at the recommended dose have been reported. Treatment of poisoning following excessive use or accidental ingestion involves aspiration and gastric lavage where appropriate, and symptomatic supportive measures. Benzyl benzoate may cause CNS stimulation and convulsions if systemically absorbed in large quantities.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other ectoparasiticides, including scabicides. ATC code: P03AX01.

Benzyl benzoate is an acaricide used in the treatment of scabies and pediculosis. According to in vitro studies, there is evidence of acaricidal and ovicidal activity on the part of benzyl benzoate. Experience reports indicate clinical efficacy. The precise clinical mechanism of this action is unknown.

5.2 Pharmacokinetic properties

Absorbed benzyl benzoate undergoes rapid hydrolysis to benzoic acid and benzyl alcohol. Benzyl alcohol is oxidised to form benzoic acid and is excreted in the urine after conjugation with glycine as hippuric acid.

The percutaneous absorption of benzyl benzoate has been studied in monkeys. Following topical application, approximately 57% of the administered dose was absorbed over 4 days; absorption increased to approximately 71% under occlusive conditions. No specific findings on absorption of benzyl benzoate following epidermal use in humans are available.

5.3 Preclinical safety data

In acute oral toxicity studies, benzyl benzoate was relatively well tolerated in mice, rats and dogs. The toxicity of benzyl benzoate was also low after repeated oral and dermal administration. Cats proved an exception, reacting with particular sensitivity: even low quantities applied to their skin resulted in fatal effects. Benzyl benzoate causes substantial irritation to mucous membranes and eyes.

The results of in vitro studies on genotoxic potential conducted with benzyl benzoate were negative. No studies are available on the carcinogenic potential of benzyl benzoate. Insufficiently documented reproduction toxicity studies in rats yielded no indications of embryotoxic or teratogenic effects. No studies on fertility or peri/postnatal development are available.

6. Pharmaceutical particulars

6.1 List of excipients

Sodium Lauryl Sulphate

Cetostearyl Alcohol

Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store at temperature not exceeding 30°C. Protect from light. Keep out of the reach of children.

6.5 Nature and contents of container

100 ml solution packed in a white PET bottle affixed with a coded label bearing batch number, manufacturing date and expiry date, packed in a unit box with an insert.

6.6 Special precautions for disposal and other handling

No special requirements.

7. Marketing Authorisation Holder

Marketing Authorisation Holder and Manufacturer:

ZAIN PHARMA LTD.

Plot No: 209/13741, Colchester Park,

Go-Down No. 1, 2, 3, Off Mombasa Road,

Behind Nice and Lovely House,

P.O. Box: 100167-00101, Nairobi, Kenya.

8. Marketing Authorisation Number

9. Date of First Authorisation / Renewal of the Authorisation

03.11.2025

10. Date of Revision of the Text

03.11.2025