

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

1.1 (Invented) name of the medicinal product:

- **Generic Name/INN Name:**
Benzyl Benzoate Application BP

- **B and Name:**
Sicazyl Lotion

1.2 Strength :

Benzyl Benzoate BP 25% w/v

1.3 Pharmaceutical form :

Lotion (Liquid)

2. Pharmaceutical form:

- **Dosage Form:** Lotion (Liquid)
- **Visual & Physical characteristics of the product:** White coloured lotion

3. Clinical particulars:

3.1 Therapeutic indications:

Benzyl Benzoate is an acaricide used in the treatment of scabies. Scabies is caused by the mite known as the *Sarcoptes scabiei*. These mites burrow under the skin and cause intense irritation and itching. The eggs laid by the mites are easily transferred to others, so spreading the infection.

Sicazyl Lotion works by killing mites by acting on their nervous system.

3.2 Posology and method of administration:

Topical use, cutaneous use.

If your skin has any cream, lotion, ointment or oil on it, wash, rinse, and dry your skin well before applying Sicazyl Lotion. If you take a bath or shower before using Sicazyl Lotion, dry the skin well before applying the medicine. Apply enough medicine to cover the entire skin surface from the neck down, including the soles of your feet, and rub in well. Allow the medicine to remain on the body for 24 hours. Then, thoroughly wash the body with warm water and soap. Rinse thoroughly and dry with clean towel. Immediately after using Sicazyl Lotion, wash your hands to remove any medicine that may be on them. Treatment may need to be repeated for severe infestation. Avoid contact with eyes.

Or as directed by the physician.

3.3 Contraindications:

Hypersensitivity to Sicazyl Lotion is a contraindication. In addition, Sicazyl Lotion should not be used if you have the following conditions:

- Hypersensitivity

3.4 Special warnings and precautions for use:

-Warnings:

Make sure you tell your doctor if you have any other medical problems, especially:

If you are pregnant, trying for a baby or breast-feeding.

If you suffer from eczema.

If you have ever had an allergic reaction to this or any other medicine.

If you are using any other preparations, including those available to buy without a prescription, herbal and complementary medicines.

- precautions:

If you are a breast-feeding mother, avoid breast-feeding until you have completed treatment with Sicazyl Lotion and all of the lotion is washed off.

The itching associated with scabies can continue for some weeks after the skin mites are destroyed. Ask your doctor or pharmacist for something to help relieve the Itching.

Do not allow Sicazyl to come into contact with the eyes or mucous membranes (e.g. mouth, vagina, inside of nose etc.), unless you are advised to do so by your doctor.

Do not apply Sicazyl Lotion to broken skin.

Complete the full course of treatment with Sicazyl Lotion; otherwise your Infection may comeback.

Clothing and bed linen should be washed after treatment

If your condition does not seem to be getting better after seven days, consult your doctor for advice.

Avoid contact with eyes.

If swallowed seek medicine attention.

3.5 Interaction with other medicinal products and other forms of interaction:

None reported.

3.6 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.

3.7 Effects on ability to drive and use machines:

Presumed to be safe and unlikely to produce an effect.

3.8 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.

3.9 Overdose:

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

4. Pharmacological properties:

4.1 Pharmacodynamic properties:

Benzyl Benzoate is an acaricide used in the treatment of scabies. Sicazyl Lotion works by killing mites by acting on their nervous system.

4.2 Pharmacokinetic properties:

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

4.3 Preclinical safety data

No further information available.

5. Pharmaceutical particulars:

5.1 List of Excipients: Sodium phosphate monobasic, Cetostearyl alcohol, Liquid paraffin, Polyethylene Glycol 1000, Propyl Hydroxy Benzoate, Methyl Hydroxy Benzoate, Purified water.

5.2 Incompatibilities:

None Known

5.3 Shelf life:

36 Months

5.4 Special precautions for storage:

Store below 30°C in a tightly closed container.

5.5 Nature and contents of container:

100 ml Amber glass bottle, packed with a leaflet in a mono carton.

5.6 Special precautions for disposal:

No special instructions needed

6. Marketing Authorization Holder:

Registrant:

Name : **Brassica Pharma Pvt. Ltd.**

Address : 7th Floor – Vastubh Apartment,
Off Road to Carter Road No.1,
Near Datta Pada Subway,
Borivali (E), Mumbai - 400 066
Tel No. 91-22-28704581

E-mail : info@brassicapharma.com

Manufacturer:

Name : **Brassica Pharma Pvt. Ltd.**

Address : Plot No.T-68, T-68 (PT), T-63, MIDC, Tarapur, Boisar (W),
Thane 401502, Maharashtra State, India.

E-mail : info@brassicapharma.com

7. Marketing Authorization number:

05056/07134/REN/2019

09582/08890/VAR/2024

8. Date of first authorization/ renewal :

Mar 9, 2020

9. Date of revision of the text:

31/08/2019