

## **SUMMARY OF PRODUCTS CHARACTERISTICS**

## **1.NAME OF THE FINISHED PHARMACEUTICAL PRODUCT :**

**1.1 Generic Name : Benzyl Benzoate Application**

**1.2 Strength : 25% w/v**

**1.3 Pharmaceutical Form: Topical Lotion**

## **2. QUALITATIVE & QUANTITATIVE COMPOSITION :**

Benzyl Benzoate BP 25% w/v

Oil in water emulsified base q.s.

## **3. PHARMACEUTICAL FORM**

Topical Lotion; White coloured perfumed lotion.

## **4. CLINICAL PARTICULARS**

### **4.1 Therapeutic indications**

Benzyl Benzoate application an acaricide used for the treatment of scabies and head lice (Pediculosis) of the head, body and pubic area.

### **4.2 Posology and method of administration**

**Scabies:** Apply over the whole body; repeat without bathing on the following day and wash off 24 hours later; a third application may be required in some cases.

**Head lice (Pediculosis) :** Head lice infestation (Pediculosis) should be treated using lotion only if live lice are present. A contact time of 8-12 hours or overnight treatment is recommended for lotions; a 2-hour treatment is not sufficient to kill eggs. In general, 2 applications of product for 7 days apart to prevent lice emerging from any eggs that survive the first application.

Not recommended for children- dilution to reduce irritant effect also reduces efficacy.

#### **4.3 Contraindications:**

Do not use Benzyl Benzoate on open wounds, such as cuts or sores on the skin or scalp. To do so may increase the amount of absorption, which may increase the chance of side effects. Known hypersensitivity to Benzyl Benzoate.

#### **4.4 Special warnings and special precautions for use:**

Benzyl Benzoate is not recommended for children, avoid contact with eyes and mucous membranes such as the inside of the nose, because it may cause irritation; do not use on broken or secondarily infected skin; It should not be applied to acutely inflamed or broken skin.

#### **4.5 Interaction with other FPPs and Other forms of Interaction**

No interactions are known.

#### **4.6 Pregnancy and lactation**

Benzyl Benzoate may be applied safely during pregnancy. It should be suggested that suspend breast-feeding until product has been washed off.

#### **4.7 Effects on ability to drive and use machines**

Not Known

#### **4.8 Undesirable effects**

Excessive topical use Benzyl Benzoate 25% w/v Application may cause uncontrolled shaking of the body.

#### **4.9 Overdose**

If ingested, Benzyl Benzoate may cause stimulation of CNS and convulsion. Systemic symptoms have been reported following excessive topical use. Treatment of poisoning involves gastric lavage if accidentally ingested. If convulsions occur they should be treated with intravenous diazepam.

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

**Pharmacotherapeutic group:** Antiscabies

**Mechanism of action:**

Benzyl Benzoate is used to treat scabies. Scabies is a skin infection caused by the mite *Sarcoptes scabiei*. It is characterized by severe itching (particularly at night), red spots, and may lead to a secondary infection. Benzyl Benzoate is lethal to this mite and so is useful in the treatment of scabies. It is also used to treat lice infestation of the head and body. Benzyl Benzoate is effective for scabies but is not a first choice for scabies. Benzyl Benzoate exerts toxic effects on the nervous system of the parasite, resulting in its death. It is also toxic to mite ova, though its exact mechanism of action is unknown. In vitro, Benzyl Benzoate has been found to kill the *Sarcoptes* mite within 5 minutes.

## 5.2 Pharmacokinetic properties

Some studies have suggested some percutaneous absorption of Benzyl Benzoate, however the amount was not quantified. Rapidly hydrolyzed to Benzoic acid and Benzyl alcohol, which is further oxidized to Benzoic acid. The benzoic acid is conjugated with Glycine to form Hippuric acid.

## 5.3 Preclinical safety data

None Known

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of Excipients

| Ingredients                  | Spec. |
|------------------------------|-------|
| Cetomacrogol Emulsifying Wax | BP    |
| Perfume Rose C-8536          | IH    |
| Purified Water               | BP    |

### 6.2 Incompatibilities

Not Known

### 6.3 Shelf life

36 months

### 6.4 Special precautions for storage

Store at a temperature not exceeding 30<sup>0</sup>C. Protect from light. Keep out of reach of children. Shake well before use.

### 6.5 Nature and contents of container

- i) 100 ml in a well closed pet bottle.
- ii) 500 ml in a well closed pet bottle.
- iii) 2.5 Ltrs. in a well closed HDPE jar.

### 6.6 Instructions for use and handling

Please see the package insert.

## 7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS

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**8. MARKETING AUTHORISATION NUMBER**

**05332/07157/REN/2019**

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

**Sep 9, 2020**

**10. DATE OF REVISION OF THE TEXT**

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