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## **SUMMARY OF PRODUCT CHARACTERISTICS BEBE LOTION**

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### **BEBE LOTION**

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## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **BEBE LOTION**

#### **1. Name of the medicinal product**

BEBE LOTION

#### **2. Qualitative and quantitative composition**

Label Claim:	
Benzyl Benzoate BP	25% w/v

For a full list of excipients, see section 6.1.

#### **3. Pharmaceutical form**

Lotion

#### **4. Clinical particulars**

##### **4.1 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. Bebe Lotion works by killing mites by acting on their nervous system.

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

If your skin has any cream, lotion, ointment or oil on it, wash, rinse, and dry your skin well before applying Bebe Lotion. If you take a bath or shower before using Bebe 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 Bebe Lotion, wash your hands to remove any medicine that may be on them. Treatment may need to

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be repeated for severe infestation. Avoid contact with eyes. Or as directed by the physician.

#### **Recommended dose and dosage schedule**

Apply gently with a pad of cotton wool to the affected parts as required.

#### **4.3 Contraindications**

Hypersensitivity to Bebe Lotion is a contraindication.

In addition, Bebe Lotion should not be used if you have the following conditions:

- Hypersensitivity

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

For external use only.

Keep all medicines away from children.

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.

Do not allow Bebe Lotion 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 Bebe Lotion to broken skin.

Complete the full course of treatment with Bebe 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.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

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Not relevant.

#### **4.6 Fertility, pregnancy and lactation**

If you are a breast-feeding mother, avoid breast-feeding until you have completed treatment with Bebe 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.

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**

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.

#### **4.9 Overdose**

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

### **5. Pharmacological properties**

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#### **5.1 Pharmacodynamic properties**

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

#### **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 data available.

### **6. Pharmaceutical particulars**

#### **6.1 List of excipients**

Lanet wax  
Cetyl Alcohol  
Stearic Acid  
Borax  
Sodium Benzoate  
Tween 80

#### **6.2 Incompatibilities**

None known

#### **6.3 Shelf life**

36 months

#### **6.4 Special precautions for storage**

Do not store above 30°C

#### **6.5 Nature and contents of container**

Bottle:	Amber PET
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## **SUMMARY OF PRODUCT CHARACTERISTICS**

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Closures:	28mm ROPP, tamper evident, child resistant.
Pack Sizes:	100ml.

#### **6.6 Special precautions for disposal and other handling**

No special requirements.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required (these should be disposed of in line with local requirements). These measures will help to protect the environment.

#### **7. Marketing authorisation holder**

**MAGZO PHARMACEUTICAL AND LABS**

**25 CRESTFIELD AVENUE, PEACE ESTATE, GAMA KWARI, JABA, KANO STATE**

**08066894569**

#### **8. Manufacturer**

**Magzo Pharmaceutical & Labs Ltd, No.25, Crestfield Avenue, Peace Estate, Gama Kwari Jaba, Nassarawa LGA, Kano State**