

1.6.	Product Information
1.6.1	Prescribing Information(Summary of Products Characteristics)

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8. Marketing authorization number
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1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

Opele Lotion

1.1 Strength

The Lotion contains 25% w/v Benzyl Benzoate in emulsion form

1.2 Pharmaceutical Form

Emulsion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

2.1 Qualitative declaration

Benzyl Benzoate BP

2.2 Quantitative declaration

The Lotion contains 25% w/v Benzyl Benzoate in emulsion form

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Emulsion

A smooth, white emulsion with a characteristic smelly odour of benzyl benzoate

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Opele Lotion is used as a treatment of scabies and pediculosis and as an insect repellent.

4.2 Posology and Method of Administration

Posology

After a light scrub all over preferably in a hot bath to open up burrows, immediately after drying, Opele Lotion is applied using cotton wool or clean cloth on the entire body below the head. The process is repeated every 12 hours for four consecutive days.

In the case of a family member contracting scabies or pediculosis, it is recommended that all family members should apply the lotion on the whole body for preventive purposes.

Opele Lotion is also used as an insect repellent. Clothes and beddings should be soaked in a diluted solution. (1bottle of Opele in a bucket of water)



Paediatric Population

There are no specific special warnings and precautions for children under 3 years. However, if there are children who are hypersensitive or allergic should avoid using Opele Lotion.

4.3 Method of Administration

Topical (External Use Only)

4.4 Contraindications

Opele Lotion is contraindicated with patients hypersensitive to benzyl benzoate

4.5 Special Warnings and Precautions for Use

Avoid contact with the eyes and mucous membranes, do not use on broken or secondarily infected skin.

4.6 Paediatric Population

There are no specific special warnings and precautions for children under 3 years. However, if there are children who are hypersensitive or allergic should avoid using Opele Lotion.

4.7 Interaction with other medicinal products and other forms of interaction

There are no known interaction of Benzyl Benzoate with other medicinal products and other forms of interaction.

4.8 Additional information on special populations

The contraindications, special warnings and precautions and interaction with other medicinal products of Opele Lotion do not affect any special populations.

4.9 Fertility, pregnancy and lactation

There is no information of safety in pregnancy and lactation.

Opele Lotion should be used with caution.

4.10 Effects on ability to drive and use machines

It does affect the ability to drive and use machines because it can cause drowsiness or dizziness.

4.11 Undesirable effects

Opele Lotion may cause skin irritation and temporary burning sensation that may be an indication for diluting the lotion for the next application.

4.12 Overdose

When ingested, benzyl benzoate may cause stimulation of the CNS (Central Nervous System) and convulsions.

Treatment of Benzyl Benzoate Overdose

Treatment of poisoning involves gastric lavage and appropriate symptomatic measures.



5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group and ATC Code:

Pharmacotherapeutic group: **Other Ectoparasiticides including scabicides**

ATC Code: **P03AX01**

Benzyl Benzoate

Benzyl benzoate is an acaricide used in the treatment of scabies and pediculosis.

Mechanism of Action:

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

Benzyl Benzoate

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

5.3 Preclinical safety data

In experimental animals, ingestion of benzyl benzoate leads to progressive incoordination, excitation, convulsions and death. There is no evidence of mutagenicity or teratogenicity.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Stearic Acid, Triethanolamine, Purified Water

6.2 Incompatibilities

None known

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store in a cool dry place below 30°C. Protect from sunlight

6.5 Nature and contents of container

Opele Lotion is packed in P40 50 ml clear glass bottles. Each bottle is sealed with 22mm aluminium ROPP cap and has a label. The bottle is then packed in a unit carton made of chipboard material.

6.6 Special precautions for disposal and other handling

No special requirements



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7. Marketing Authorisation Holder & Manufacturing Site Addresses

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8. Marketing Authorisation Number

497

9. Date of First Registration/Renewal of the Registration

Date of first authorisation: 8/1/2009

Date of latest renewal: Annual Retention

10. Date of revision of the text

November 2020



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