

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Benzyl Benzoate 25% w/v Application Cutaneous Emulsion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Active Substance</u>	<u>%w/v</u>
Benzyl Benzoate	25.0

Excipients

Also contains cetostearyl alcohol (a constituent of emulsifying wax), **E218** Methyl Hydroxybenzoate & **E214** Ethyl Hydroxybenzoate.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous emulsion
Smooth white creamy emulsion.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

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

4.2 Posology and method of administration

Topical use, Cutaneous use.

(a) Scabies

Apply thoroughly to the entire body omitting the head and neck. Thorough bathing with complete changes of clothing and bedding should follow. All contacting clothes and bedding should be washed and/or cleaned. Repeat the following day and if necessary within 5 days.

(b) 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 required.

Thorough bathing with complete changes of clothing should follow. All contacting clothing and bedding should be washed and or cleaned.

Child and Infant Dosage Instructions

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

4.3 Contraindications

Use in persons hypersensitive to the active ingredients.

4.4 Special warnings and precautions for use

Local erythema and irritation may occur.

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

Direct contacts should be treated.

If no improvement occurs consult the doctor.

E218 Methyl Hydroxybenzoate & **E214** Ethyl Hydroxybenzoate may cause allergic reactions (possibly delayed)

4.5 Interaction with other medicinal products and other forms of interaction

None reported.

4.6 Fertility, 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.

4.7 Effects on ability to drive and use machines

Presumed to be safe and unlikely to produce an effect.

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.

4.9 Overdose

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

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 further information available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Emulsifying Wax (cetostearyl alcohol, sodium laurilsulfate, purified water)

Phenoxyethanol

E218 Methyl Hydroxybenzoate

E214 Ethyl Hydroxybenzoate
Purified Water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

150ml. Glass Winchester with tamper evident cap.

1 litre Polyethylene terephthalate container.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Ovelle Ltd,
Industrial Estate,
Coe's Rd,
Dundalk,
Co. Louth

8 MARKETING AUTHORISATION NUMBER

PA 0206/023/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 September 1988

Date of last renewal: 01 September 2008

10 DATE OF REVISION OF THE TEXT

March 2014