Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Benzyl Benzoate 25% w/v Application Cutaneous Emulsion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance	%w/v
Benzyl Benzoate	25.0

Excipients
Constituents of emulsifying wax (Cetostearyl alcohol is present at 2.16 % $^{w}/_{v}$ and **E487** sodium laurilsulfate is present at 0.24 % $^{w}/_{v}$)
E218 Methyl Hydroxybenzoate is present at 0.165 % w/v
E214 Ethyl Hydroxybenzoate is present at 0.11% w/v
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 at night from the soles of the feet, omitting the head and neck, for 2 consecutive nights. The lotion is left in place for 8-12 hours on each night and may be followed by a repeated application at night 7 days later. In the case of lesions affecting the head, face and/or neck, it may be necessary to consult a healthcare professional before using this product. Thorough bathing with complete changes of clothing and bedding should follow each application. All contacting clothes and bedding should be washed and/or cleaned.

(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 repeated after 7 and 14 days.

Thorough bathing with complete changes of clothing should follow each application. 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).

Sodium laurilsulfate (E 487) may cause local skin reactions (such as stinging or burning sensation) or increase skin reactions caused by other products when applied on the same area.

Sensitivity to Sodium laurilsulfate (SLS) can vary according to body site, age and patient population as well as other factors such as hydration level, skin colour and disease. Patient populations with decreased skin barrier functions such as in atopic dermatitis are more sensitive to the irritant properties of SLS.

4.5 Interaction with other medicinal products and other forms of interactions

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.

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. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie.

4.9 Overdose

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

P03AX01 Other ectoparasiticides, incl. Scabicides

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, **E487** sodium laurilsulfate)
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 Limited
Industrial Estate
Coe's Road
Dundalk
Co. Louth
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0206/023/001

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

April 2019