

Product Name, Volume & Packaging Description: Ovelle Benzyl Benzoate 25% Application 150ml 5 Page label

Dimensions: 50 x 105mm 5 page label

Ovelle Purchasing Code, Rev. and Draft #: 9405 Rev000 V4

Created By: Conor McEneaneyDate: 23/09/2015

Completed Artwork Checklist (to be completed by designer)

Y / NA: Product NameY / NA: For external use only

Y / NA: VolumeY / NA: PAO Symbol

Y / NA: LogosY / NA: Recycle Symbol

Y / NA: DescriptionY / NA: Code & Revision

Y / NA: DirectionsY / NA: Barcode

Y / NA: PrecautionsY / NA: Barcode Scanned?

Y / NA: Storage / Expiry InstructionsY / NA: PIF Holder

Y / NA: Other Products / Also AvailableY / NA: Website

Y / NA: IngredientsY / NA: Made in Ireland

Y / NA: Braille

Signed:Date:

Marketing/Sales Approval:Date:

QA Approval:Date:

QP Approval:Date:

KeylineBraillePMS Cool Grey 8CPMS 3115C

Re-Seal KillGlue

Ovelle Pharmaceuticals, Coe's Road, Dundalk, Ireland
Tel: +353 42 9332304

PAGE 1

50 x 105mm 5 PAGE LABEL KEYLINE

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OVELLE

150ml

BENZYL BENZOATE 25%w/v APPLICATION

Cutaneous Emulsion / Shake Bottle Well

SCABIES: Apply thoroughly to entire body omitting the head and neck. Repeat the following day and within 5 days if necessary. **PEDICULOSIS:** Apply to affected area, allow to remain on for 24 hours, wash thoroughly. In severe cases 2 or 3 treatments may be required. Thorough bathing with complete change of clothing and bedding should follow. All contacting clothing and bedding should be washed and or cleaned. **CHILDREN & INFANTS:** Benzyl Benzoate 25%w/v Application may be diluted with an equal quantity of water for older children and with three parts of water for infants. **PRECAUTIONS & WARNINGS:** Not to be used by persons hypersensitive to the active ingredient. Local erythema and irritation may occur. Cetostearyl Alcohol may cause local skin reactions (e.g. contact dermatitis). E218 Methyl Hydroxybenzoate & E214 Ethyl Hydroxybenzoate may cause allergic reactions (possibly delayed). Please refer to the leaflet for further information. Keep out of reach and sight of children. Do not store above 25°C. Avoid contact with eyes. **INGREDIENTS:** Benzyl Benzoate 25%w/v, Emulsifying Wax (Cetostearyl Alcohol, Sodium Laurilsulfate, Purified Water), Phenoxethanol, E218 Methyl Hydroxybenzoate, E214 Ethyl Hydroxybenzoate, Purified Water.

PA holder and manufacturer: Ovelle Ltd., Dundalk, Ireland. PA 206/23/1

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PATIENT INFORMATION LEAFLET - BENZYL BENZOATE 25%w/v APPLICATION (Cutaneous Emulsion) Benzyl Benzoate 25%w/v

Read all of this leaflet carefully because it contains important information for you. This medicine is available without a prescription. Nevertheless you will still need to use Benzyl Benzoate 25%w/v Application carefully to get the best results from it. • Keep this leaflet. You may need to read it again. • Ask your pharmacist if you need more information or advice. • You must see a doctor if your symptoms do not improve after using Benzyl Benzoate 25%w/v Application.

IN THIS LEAFLET

1: What Benzyl Benzoate 25%w/v Application is and what it is used for. 2: Before you use Benzyl Benzoate 25%w/v Application

3: How to use Benzyl Benzoate 25%w/v Application. 4: Possible side effects. 5: How to store Benzyl Benzoate 25%w/v Application. 6: Further information

1. WHAT BENZYL BENZOATE 25%W/V APPLICATION IS AND WHAT IT IS USED FOR

The name of your treatment is Benzyl Benzoate 25%w/v Application. It is a smooth white creamy emulsion. Benzyl Benzoate 25%w/v Application contains Benzyl Benzoate 25%w/v as the active ingredient. This application is used for the treatment of scabies and pediculosis (ie hair or body lice). **SCABIES** is a persistent itchy skin eruption caused by cutaneous infestation with mites. The itch is worse after bathing and at night. Scabies affects all races and social classes world wide. **PEDICULOSIS** is a relatively common problem in school children in various parts of the world. Females of all ages are more frequently infected than males. There does not appear to be any direct correlation between hair length and infestation rates.

2. BEFORE YOU USE BENZYL BENZOATE 25%W/V APPLICATION

Do not use Benzyl Benzoate 25%w/v Application • If you are allergic to Benzyl Benzoate or any of the other ingredients of this medicine listed in section 6, **Warnings and Precautions** • Skin can become red and irritated at the site of application.

GLUE

8mm BATCHING AREA, KEEP FREE FROM ARTWORK.

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GLUE

• 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). **Other medicines and Benzyl Benzoate 25%w/v Application** • Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. **Pregnancy, breast-feeding and fertility** • Ask your doctor or pharmacist for advice before taking any medicine. **Benzyl Benzoate 25%w/v Application contains** Emulsifying Wax (Cetostearyl Alcohol, Sodium Laurilsulfate, Purified Water), Phenoxethanol, E218 Methyl Hydroxybenzoate, E214 Ethyl Hydroxybenzoate and Purified Water.

3. HOW TO USE BENZYL BENZOATE 25%W/V APPLICATION

• **Treating Scabies:** Apply thoroughly to the entire body omitting the head and face. Thorough bathing with a complete change 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. • **Treating Pediculosis:** Apply to 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 a complete change of clothing and bedding should follow. All contacting clothes and bedding should be washed and/or cleaned. • **Children and Infants:** Benzyl Benzoate 25%w/v Application may be diluted with an equal quantity of water for older children and with 3 parts of water for infants. **If you use more Benzyl Benzoate 25%w/v Application than you should:** Treatment of poisoning involves aspiration and lavage and appropriate symptomatic measures. **If you forget to use Benzyl Benzoate 25%w/v Application:** Apply Benzyl Benzoate 25%w/v Application as soon as you remember it.

4. POSSIBLE SIDE EFFECTS

Benzyl Benzoate 25%w/v Application may cause irritation to the eyes and mucous membranes (e.g nostrils, mouth, lips, ears

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and genital area). If swallowed or following excessive topical use Benzyl Benzoate 25%w/v Application may cause uncontrolled shaking of the body. If you experience any of these symptoms please see your doctor or pharmacist or in severe cases go to your nearest Accident and Emergency Department.

5. HOW TO STORE BENZYL BENZOATE 25%W/V APPLICATION

Keep out of reach and sight of children. Store below 25°C. Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Benzyl Benzoate 25%w/v Application contains: The active substance is Benzyl Benzoate. The other ingredients are Emulsifying Wax (Cetostearyl Alcohol, Sodium Laurilsulfate, Purified Water), Phenoxethanol, E218 Methyl Hydroxybenzoate, E214 Ethyl Hydroxybenzoate and Purified Water. **What Benzyl Benzoate 25%w/v Application looks like and contents of the pack:** Benzyl Benzoate 25%w/v Application is a smooth white creamy emulsion for topical application to the skin. It is available in 150ml and 1Liter bottle sizes.

MARKETING AUTHORISATION HOLDER AND MANUFACTURER

The Marketing Authorisation holder and the manufacturer is Ovelle Ltd.,Coe's Road, Dundalk, Co Louth, Ireland.
Tel: +353 (0) 42 93 32304.
This label was last reviewed in July 2015

GLUE

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BRILLE ON PAGE 1

OVELLE

150ml

BENZYL BENZOATE 25%w/v APPLICATION

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BENZYL BENZOATE 25%w/v APPLICATION

2 5 % w / v

APPLICATOR

