

# **BENZYL BENZOATE 25%w/v APPLICATION CUTANEOUS EMULSION**

benzyl benzoate 25% w/v

## **PATIENT INFORMATION LEAFLET**

*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:**

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## **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 (i.e. body or head 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.
- Direct contacts should be treated.
- If no improvement occurs consult the doctor.

### ***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, E487 sodium laurilsulfate,), Phenoxyethanol, E218 Methyl Hydroxybenzoate, E214 Ethyl Hydroxybenzoate and Purified Water.

Excipients warnings:

- Cetostearyl Alcohol may cause local skin reactions (e.g. contact dermatitis)
- This medicine contains 0.24ml Sodium laurilsulfate in each 100 ml volume. E487 Sodium laurilsulfate 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.
- E218 Methyl Hydroxybenzoate & E214 Ethyl Hydroxybenzoate may cause allergic reactions (possibly delayed)

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

### **• Treating 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 a complete change of clothing and bedding should follow each application. All contacting clothes and bedding should be washed and/or cleaned.

### **• 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 repeated after 7 and 14 days. Thorough bathing with a complete change of clothing and bedding should follow each application. 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 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.

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRRA Pharmacovigilance, website: [www.hpra.ie](http://www.hpra.ie).

By reporting side effects you can help provide more information on the safety of this medicine.

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

Keep out of the sight and reach 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 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, E487 sodium laurilsulfate), Phenoxyethanol, 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 1Litre bottle sizes.

### **MARKETING AUTHORISATION HOLDER AND MANUFACTURER**

The Marketing Authorisation holder and the manufacturer is Ovelle Ltd., Coe's Road, Dundalk, Co Louth, Ireland

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