

## **PACKAGE LEAFLET: Information for the user**

### **PRODBENZOATE**

Emulsion – 25%

(Benzyl benzoate)

**Read all of this leaflet carefully before you start using this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

#### **In this leaflet:**

1. What Prodbenzoate is and what it is used for
2. Before you use Prodbenzoate
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### **1. WHAT PRODBENZOATE IS AND WHAT IT IS USED FOR**

Prodbenzoate contains the active substance benzyl benzoate, which is an acaricide, used for the treatment of scabies and pediculosis.

The 25% emulsion is applied to the whole body, from the neck down.

If applied appropriately, one treatment may suffice, although the possibility of failure is lessened by a second application within 5 days from the first application.

Your doctor may have given Prodbenzoate for another purpose. Ask your doctor if you want to know why you have been given this medicine.

## **2. BEFORE YOU USE PRODBENZOATE**

### **Do not use Prodbenzoate if:**

- you are hypersensitive (allergic) to benzyl benzoate or to any of the other ingredients of the formula.

### **Take special care with Prodbenzoate**

During the use of Prodbenzoate you must use plastic gloves and the hands must be washed properly after the application of the emulsion on the skin.

Benzyl benzoate is irritating to the eyes, so the eyes should be protected when it is used in the head (in pediculosis).

Contact with mucous membranes should be avoided!

You should be careful not to swallow benzyl benzoate.

Be careful with the children! The use in children is not recommended!

Do not use on broken or infected skin.

### **Taking other medicines**

Please tell your doctor or pharmacist if you are taking / using, have recently taken / used or might take / use any other medicines, including medicines obtained without a prescription.

Do not forget to inform your doctor for the treatment with Prodbenzoate if you receive any other medicine during treatment.

Important drug-drug interactions can be observed after the systemic absorption of Prodbenzoate.

There are no data on the interaction of benzyl benzoate with the other drugs during its topical application.

### **Pregnancy and breastfeeding**

Ask for the advice of your pharmacist or doctor before you use this drug.

The use of Prodbenzoate during pregnancy must be done only in cases it is strictly necessary.

The breastfeeding of the baby must be interrupted if the mother is being treated with benzyl benzoate and resumed only after washing the body.

### **Important information about some of the ingredients of Prodbenzoate**

Prodbenzoate emulsion contains cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).

### **3. HOW TO USE PRODBENZOATE**

Your doctor or pharmacist will inform you about the amount of Prodbenzoate that you should use and when you should use it. It is important to follow the instructions of your doctor or pharmacist promptly and never change the dose by yourself, no matter how you feel.

Ask your doctor or pharmacist if you are unsure about the dose you should use and when to use it.

In scabies: after a hot shower and wiping, the body (except the head and face) are rubbed with a cloth soaked with Prodbenzoate emulsion.

If applied appropriately, one treatment may suffice, although the possibility of failure is lessened by a second application within 5 days from the first application.

Another way is the consecutive application three times in a row of the emulsion of benzyl benzoate every 12 hours, without bathing (without having a shower) between the applications but being washed 12 hours after the last application.

Another way of application is only one application to the whole body, repeated without bathing (without having a shower) after 24 hours from the first application.

The body wash is done 24 hours after the last application.

Sometimes, a third application of benzyl benzoate emulsion may be necessary.

Generally, Prodbenzoate is not recommended for children, but if it will be used, it must be diluted before, to minimise the risk of irritation, although dilution also reduces efficacy.

#### In pediculosis

The head is rubbed with the emulsion of Prodbenzoate and after 24 hours is washed with water and soap. A week after the last treatment, a careful control must be done.

In children, Prodbenzoate emulsion must be diluted according the doctor advice.

**If you use more Prodbenzoate than you should**

If you use more Prodbenzoate than you should, or if the children have used it accidentally, please contact your doctor, the nearest hospital, or call the emergency to take an opinion for the risk and advice about the actions to be taken.

Systemic symptoms have been reported on excessive topical use of Prodbenzoate.

If benzyl benzoate is swallowed, gastric-emptying should be done within an hour of receiving the above mentioned substance.

In case of poisoning from excessive topical use, the skin should be washed properly.

Also, if it is necessary, appropriate measures must be taken for the other symptoms shown during overdose.

**If you forget to use Prodbenzoate**

If you forget to use one dose (or more doses), use the next dose in its usual time.

Do not use a double dose (or higher) to make up the forgotten dose (doses).

If you have further questions about the use of this drug, ask your doctor or pharmacist.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, Prodbenzoate can cause side effects, although not everybody gets them.

Most side effects are dose-related and they disappear when the dose is reduced or the treatment is interrupted.

Some side effects may happen at the beginning of treatment and disappear spontaneously during treatment.

Prodbenzoate emulsion is irritant to the eyes and mucous membranes and also it may cause a slight irritation to the skin and a transient burning sensation.

If ingested, benzyl benzoate may cause stimulation of the CNS and convulsions.

In case of severe skin reactions, the emulsion must be removed as soon as possible, washing the body. Also you should consult your doctor as soon as possible.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## **5. HOW TO STORE PRODBENZOATE**

Keep this medicine out of the reach and sight of children!

Do not use the medicine after the expiry date which is stated on the package!

Store at a temperature below 25°C!

Store in the original package protected from light and humidity!

## **6. OTHER INFORMATION**

**What Prodbenzoate 25% emulsion contains**

**The active substance is** benzyl benzoate.

1 ml emulsion contains 250 mg benzyl benzoate.

**The other ingredients are:** cetostearyl alcohol, sodium lauryl sulfate, polysorbate 80, purified water.

**Content of the pack**

Plastic bottle of 200 ml.

**Marketing Authorisation Holder (MAH) and Manufacturer:**

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**This leaflet was last revised in January 2024.**