

## **Package leaflet: Information for the user**

### **BENZOTAL, 200 mg/g ointment**

Benzyl Benzoate

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to your doctor if you do not feel better or if you feel worse after 14 days.

#### **What is in this leaflet**

1. What Benzotal is and what it is used for
2. What you need to know before you use Benzotal
3. How to use Benzotal
4. Possible side effects
5. How to store Benzotal
6. Contents of the pack and other information

#### **1. What Benzotal is and what it is used for**

Benzotal ointment is a topical medicine used against parasites for the treatment of scabies.

#### **2. What you need to know before you use Benzotal**

##### **Do not use Benzotal:**

- if you are allergic to benzyl benzoate or any other ingredients of this medicine (listed in section 6).

##### **Warnings and precautions**

Avoid contact of the ointment with eyes, mucous membranes or injured skin to avoid irritation.

It is recommended to use a small amount of the ointment on the skin at first to be sure that you are not allergic to the medicine.

##### **Other medicines and Benzotal**

No interactions with other medicines have been noted.

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, consult your doctor or pharmacist for advice before taking this medicine.

The ointment may be used during pregnancy. Breastfeeding must be stopped during the treatment, after washing off the ointment, breastfeeding may be continued. Ask your doctor or pharmacist for advice before taking any medicine.

### **Driving and using machines**

Benzotal does not influence the ability to drive or use machines.

### **Benzotal contains bronopol, methyl parahydroxybenzoate (E 218) and propyl parahydroxybenzoate (E 216).**

Bronopol may cause local skin reactions (for example contact dermatitis).

Methyl parahydroxybenzoate and propyl parahydroxybenzoate may cause allergic reactions (also delayed-type).

## **3. How to use Benzotal**

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

When you starting to it for the first time, press the cap of the tube backwards towards the foil film at the top of the tube.

10-15 g of ointment is applied to the skin. The ointment is applied to pre-washed skin and is rubbed in. First the ointment is applied to the hands, arms and then to other lower parts of the body. Finally, the ointment is applied to legs, feet and between the toes. All of the skin of children is covered with the ointment; in adults the face and scalp are left uncovered. Areas with delicate skin (inguinal area, genitals, breasts), also in eczema (reddened and non-infectious rash) and inflamed skin areas, the ointment must be applied carefully, without rubbing it into the skin.

After using the ointment, the hands may not be washed for 3 hours. After every hand wash, the ointment must be applied again. The whole body may be washed only after 3 days. It is important that clean underwear and clothes are used after using the ointment.

The ointment is applied 4 times during 2 weeks (every 3-4 days). A treatment course usually requires 60-90 g of ointment (2-3 tubes).

Benzotal is for external use only! Do not swallow!

### **If you use more Benzotal than you should**

If a very large amount of the ointment is applied on the skin, a central nervous system excitation (seizures) and/or urine retention may occur. If these symptoms occur, it is necessary to wash the ointment off the skin, and if needed, administer anti-seizure medicines.

Turn to the doctor immediately if you suspect overdose or experience symptoms of overdose. Take the medicine package with you to the doctor.

### **What should you do if you accidentally ingest Benzotal?**

Accidental ingestion of the ointment may produce central nervous system excitation (seizures) and/or urine retention. If these symptoms occur, it is necessary to wash the ointment off the

skin, and if needed, administer anti-seizure medicines. After accidental ingestion of the ointment, if possible, perform gastric lavage repeatedly and inhibit the adsorption of the ointment with active charcoal. Turn to the doctor immediately if you have accidentally ingested the ointment. Take the medication package with you to the doctor.

#### **If you forget to use Benzotal**

Use it as soon as possible and thereafter continue as usual. If it is already the time for the next application, use the prescribed amount and then continue as usually. Do not take a double dose to make up for a forgotten dose.

**If you stop using Benzotal** before the end of the course the treatment may be ineffective. If you have any further questions on the use of this medicine, consult your doctor or pharmacist.

#### **4. Possible side effects**

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

Local side effects. After rubbing in the ointment itchy feeling may appear that goes away in a few minutes. In skin oversensitivity the use of Benzotal may cause skin irritation or burning feeling. If side effects occur you must stop using the medicine and wash the ointment off the skin.

#### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via [www.ravimiamet.ee](http://www.ravimiamet.ee). By reporting side effects, you can help provide more information on the safety of this medicine.

#### **5. How to store Benzotal**

Store below 25 °C.

Do not refrigerate or freeze.

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

Do not use this medicine after the expiry date which is stated on the carton. 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. Contents of the pack and other information**

##### **What Benzotal contains**

- The active ingredient is benzyl benzoate (*Benzylis benzoas*).

- Other ingredients are polysorbate (E 80), carbomer, sodium hydroxide, methyl parahydroxybenzoate (E 218), propyl parahydroxybenzoate (E 216), bronopol and purified water.

**What Benzotal looks like and contents of the pack**

White or almost white ointment with a specific smell.

30 g ointment in aluminium tube, aluminium tube in carton box.

**Marketing Authorisation Holder**

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