

## PACKAGE LEAFLET: Information for the user

### IKTIOL

#### Ointment – 10%

(Ichthammol)

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

- Keep this leaflet. You may need to read it again.
- If you have any further question, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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

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

#### **1. WHAT IKTIOL IS AND WHAT IT IS USED FOR**

Iktiol contains ichthammol which has an antiseptic, antiparasitic and keratolytic action. It is for external dermatological use only. It is locally used in eczematous dermatitis, especially in chronic eczema when there is a deep desquamation, in psoriasis and erysipelas. Due to its anti-inflammatory and antiseptic properties and the stimulation of blood circulation, Iktiol improves the symptoms of inflammation. In cases with purulent problems in advanced stages of inflammation, it softens the infection hearth and drows out the infection by pulling the pus to the

surface. Iktiol is suitable for most cases but may not be preferable because of its visibility and unpleasant odour or since it is not recommended to be applied on face.

## **2. WHAT YOU NEED TO KNOW BEFORE YOU USE IKTIOL**

### **Do not use Iktiol:**

- if you are allergic to ichthammol or to any of the other ingredients of the ointment.

### **Warnings and precautions**

For dermatological use only. Do not use in mucosa, eyes, nostrils.

### **Other medicines and Iktiol**

Tell your doctor or pharmacist if you are taking / using, have recently taken / used or might take / use any other medicines. Inform your doctor that you are using Iktiol if you take / use any other medicine during treatment. However, the clinical experience has not identified any interaction between Iktiol and other medicines as a result of their simultaneously local or systemic administration.

### **Pregnancy and breastfeeding**

**Ask for the advice of the doctor or pharmacist before using this medicinal product.**

There are no adequate studies for the possible effects of Iktiol in pregnancy and breastfeeding.

### **Driving and using machines**

The effect of this medicine on the ability to drive and use machines is not harmful.

## **3. HOW TO USE IKTIOL**

Always use Iktiol exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. If you feel that the effect is too strong or too weak, talk to your doctor or pharmacist.

For the treatment of chronic eczema forms described above, is recommended the application of a sufficient quantity of ointment to cover the affected area of skin, 1-3 times daily. The applied

dose is dependent on the total surface of the affected skin. Your doctor will decide if the dose should be increased or decreased.

The therapy should start as soon as possible when the first symptoms appear.

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

If you use more Iktiol than you should, or if your child has used it by mistake, contact your doctor or call the hospital so you will be advised for the possible risk and the actions to take. Overdose cases are not known because the skin absorption is minimal.

#### **If you forget to use Iktiol**

If you forget to use a dose (or more), use the next dose at the normal time.

Do not use a double dose (or higher) to substitute the forgotten dose/s.

If you have any further questions, ask your doctor or pharmacist.

### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them. Most of the effects are dose-dependent and disappear when the dose is reduced or the treatment is interrupted. Some of them may appear at the beginning and disappear spontaneously during treatment.

The undesirable effects are:

- irritations
- hypersensitivity skin reactions.

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

### **5. HOW TO STORE IKTIOL**

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 package.

Do not store above 25°C.

Keep in the original package to protect from light.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What Iktiol contains?**

**The active substance** is ichthammol (ammonium sulfoichthiolate).

1 g ointment contains 100 mg ichthammol.

**The other ingredients** are: white soft paraffin, light liquid paraffin.

### **Content of the pack**

Carton box with 1 tube of 20 g.

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

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

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