

## PACKAGE LEAFLET

### Package leaflet: Information for the user

#### **Solket inflammation and pain 1.6% mouthwash** Ketoprofen Lysine salt

**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 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 a doctor if you do not feel better or if you feel worse after a short period.

#### **Content of this leaflet:**

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

#### **1. What SOLKET inflammation and pain is and what it is used for**

SOLKET inflammation and pain contains the active substance ketoprofen lysine salt, which belongs to a group of medicines called non-steroidal anti-inflammatory drugs ("NSAIDs") used to relieve pain and inflammation.

This medicine is used as a symptomatic treatment in case of irritation and / or inflammation of the mouth and pharynx (eg gingivitis, stomatitis, pharyngitis), even after dental treatment as caries or tooth extraction.

Talk to your doctor if you do not feel better or if you feel worse after a short period of treatment.

#### **2. What you need to know before you use SOLKET inflammation and pain**

##### **Do not use SOLKET inflammation and pain**

- if you are allergic to ketoprofen lysine salt or any of the other ingredients of this medicine (listed in section 6);
- if you know you are allergic or have suffered from asthma, allergic urticaria or allergic type (rhinitis), as a result of the use of this medicine or of other non-steroidal anti-inflammatory drugs (NSAIDs), such as aspirin;
- if you are pregnant or breast-feeding (see section "Pregnancy and breast-feeding").

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

Talk to your doctor or pharmacist before using SOLKET inflammation and pain.

The use of this medicinal product, especially if prolonged, may give rise to sensitization phenomena (increased response with the repetition of the same dose of drug) or local irritation; in these cases it is necessary to interrupt the treatment and consult the doctor who can define a suitable therapy.

Do not use this medicine for long periods.

For those who play sports, the use of medicines containing ethyl alcohol may result in positive doping tests in relation to the limits of alcohol concentration indicated by some sports federations.

### **Other medicines and SOLKET inflammation and pain**

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

There are no known interactions with other medicines.

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

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

Do not use SOLKET inflammation and pain if you are pregnant or breast-feeding.

### **Driving and using machines**

Use of this medicinal product does not affect the ability to drive or use machines.

### **SOLKET inflammation and pain contains ethanol (ethyl alcohol), para-hydroxybenzoates and green color (quinoline yellow and patent blue V)**

This medicinal product contains small amounts of ethanol (ethyl alcohol), less than 100 mg per dose.

This medicinal product contains para-hydroxybenzoates (methyl para-hydroxybenzoate and propyl-parahydroxybenzoate) which may cause allergic reactions (even delayed).

This medicinal product contains the quinoline yellow dye (E104) and the blue patent dye V (E131) which may cause allergic reactions.

## **3. How to use SOLKET inflammation and pain**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. If you are not sure, talk to your doctor or pharmacist.

### **Instructions on use**

- Open the bottle, keeping the cap firmly pressed and turning counter-clockwise at the same time.
- Rinse or garnish.

Do not exceed the recommended dose.

### **If you use more SOLKET inflammation and pain than you should**

No cases of overdose have been reported during treatment with this medicinal product.

If you swallow the amount corresponding to the recommended dose of SOLKET inflammation and pain, this does not result in damage as this dose is equal to that usually used orally.

In case of accidental ingestion/intake of an overdose of this medicinal product, notify your doctor immediately or contact the nearest hospital.

### **If you forget to use SOLKET inflammation and pain**

Do not use a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## **4. Possible side effects**

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

No side effects have been reported during treatment with this medicinal product.

### **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 the national reporting system at the address

<http://www.aifa.gov.it/content/segnalazioni-reazioni-avverse>. By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store SOLKET inflammation and pain**

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 pack after "EXP". The expiry date refers to the last day of that month.

The product must be used within 9 weeks of first opening the bottle. The excess product must be eliminated.

Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to eliminate the medicines you no longer use. This will help protect the environment.

## **6. Contents of the pack and other information**

### **What SOLKET inflammation and pain contains**

- The active substance is ketoprofen lysine salt: 100 ml of mouthwash contain 1.6 g of ketoprofen lysine salt, equal to 1 g of ketoprofen.
- The other ingredients are: 96% ethyl alcohol, sodium saccharin, methyl p-hydroxybenzoate, propyl p-hydroxybenzoate, mint flavor, levomentol, green dye, monobasic sodium phosphate, purified water.

### **What SOLKET inflammation and pain looks like and contents of the pack**

Package containing a 150 ml bottle of solution with safety lock and a measuring cup.

### **Marketing Authorization Holder**

Aesculapius Farmaceutici S.r.l. - Via Cefalonia, 70 - 25124 Brescia (Italy)

### **Manufacturer**

Doppel Farmaceutici S.r.l. - Via Martiri delle Foibe, 1 - Cortemaggiore (Italy)

### **This leaflet was last revised in:**

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