

**Package leaflet: Information for the user****Solket inflammation and pain 1.6% mouthwash**

Ketoprofen Lysine salt

Equivalent Medicine

**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 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 1.6% mouthwash contain the active ingredient ketoprofen lysine salt, a substance that belongs to a group of medicines called "Non-Steroidal Anti-Inflammatory Drugs" "NSAIDs", and is a stomatological medicine used for the local treatment of the oral cavity.

SOLKET inflammation and pain 1.6% mouthwash is used for the symptomatic treatment of irritative - inflammatory states also associated with pain in the oropharyngeal cavity (for example gingivitis, stomatitis, pharyngitis), also as a consequence of conservative dental therapy (tooth care) or extractive (extraction of a tooth).

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 "Contents of the pack and other information");
- if you have suffered from a breathing problem called bronchial asthma in the past.
- if you have a history of allergic reactions, such as asthma, urticaria or rhinitis, caused by the use of other non-steroidal anti-inflammatory drugs;
- if you are pregnant, if you suspect pregnancy or if you are breastfeeding (see the subparagraph "Pregnancy and breastfeeding").

**Warnings and precautions**

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

Ask your doctor for advice before using Solket inflammation and pain if you suffer or have suffered in the past from bronchial asthma.

If you use Solket inflammation and pain for prolonged periods and with high doses, keep in mind the possibility of competition between the absorbed ketoprofen and other medicines with high binding to plasma proteins.

The use, especially if prolonged, of topical medicines (for local use) could give rise to sensitization phenomena (allergy). In this case, stop treatment and contact your doctor to adopt suitable therapeutic measures.

After a short period of treatment without appreciable results, consult your doctor.

Do not use Solket inflammation and pain for prolonged treatments.

For those who carry out sporting activities, the use of medicines containing ethyl alcohol can lead to positive anti-doping tests in relation to the blood alcohol concentration limits indicated by some sports federations.

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

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

No negative interactions with other medicinal products have been reported.

#### **Pregnancy and lactation**

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

##### Pregnancy

Do not use SOLKET inflammation and pain during pregnancy.

Oral formulations (e.g., tablets) of ketoprofen may cause adverse effects on the fetus. It is not known whether ketoprofen carries the same risk when used on the skin.

##### Lactation

Do not use SOLKET inflammation and pain if you are breastfeeding with breast milk.

#### **Driving vehicles and using machinery**

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 colour (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.

**The recommended dose is:** a rinse or gargle with 10 ml of Solket inflammation and pain diluted in approximately 100 ml of water, 2 times a day.

#### **Instructions for use**

The package includes a measuring cup with a mark corresponding to 10 ml.

To open the package, press the cap firmly and rotate it counterclockwise at the same time. Any involuntary swallowing of the solution used for rinsing and gargling does not cause any particular harm.

**Warning:** Do not exceed the indicated doses.

Use only for short treatment periods.

Consult your doctor if the disorder occurs repeatedly or if you notice any recent changes in its characteristics.

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

If you use more SOLKET inflammation and pain than you should

No cases of overdose have been reported.

If you accidentally ingest/take an excessive dose of this medicine, contact your doctor immediately or go to the nearest hospital.

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

Do not use a double dose to make up for a missed 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. The following side effects may occur:

**Very rare** (may affect less than 1 in 10000 people):

- local irritative phenomena (throat irritation);
- allergic phenomena such as swelling of the face, particularly around the mouth and eyes, tongue or throat (angioneurotic edema); this occurs especially in subjects with hypersensitivity to non-steroidal anti-inflammatory drugs ("NSAIDs").

There are no known systemic side effects.  
If side effects occur, consult your doctor.

Compliance with the instructions contained in the leaflet reduces the risk of side effects.

#### Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist, including any 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: 85% glicerol, 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.

##### Manufacturer

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

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