

**Package leaflet: Information for the user****Solket inflammation and pain 0.16% oromucosal spray**

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 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 spray for oral mucosa contains 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 is used as a 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 treatment) or extraction (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 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 bronchial asthma or adverse reactions caused by the use of other non-steroidal anti-inflammatory medicines such as asthma attacks, bronchospasm (narrowing of the bronchi, causing difficulty in breathing), acute rhinitis, nasal polyps, urticaria or angioneurotic edema (swelling of the face or mucous membranes);
- if you are pregnant, if you suspect pregnancy or if you are breastfeeding (see the paragraph "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.

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 oral mucosa spray for prolonged treatments.

**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 negative interactions with other medicines.

**Pregnancy and lactation**

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.

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 and using machines**

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

**Solket inflammation and pain contains para-hydroxibenzoates**

This medicine contains para-hydroxybenzoates (methyl parahydroxybenzoate and propyl parahydroxybenzoate) which can cause allergic reactions (even delayed).

**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**

- Raise the cannula and place it in the mouth
- Direct the spray directly to the affected area.
- Press the dispenser to allow the medicine to escape

**The recommended dose is:** 1-2 sprays, up to three times a day.

Each spray contains about 0.2 ml of solution equal to 0.32 mg of Solket inflammation and pain

**Warning:** do not exceed the recommended dose.

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

**If you use more Solket inflammation and pain than you should**

No cases of overdose have been reported.

In case of accidental ingestion / intake of an overdose of Solket inflammation and pain oromucosal spray, immediately notify your doctor or go to the nearest hospital.

**If you forget to use Solket inflammation and pain**

If you forget to use a dose of the medicine, do so as soon as you remember, unless it is almost time to use your next dose.

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.

The following side effects may occur:

**Very rare** (can affect less than one person in 10000):

- 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 people allergic to non-steroidal anti-inflammatory drugs ("NSAIDs").

There are no known systemic side effects.

If you have any side effects, 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 carton after "EXP". The expiry date refers to the last day of that month.

The product must be used within 21 weeks of first opening the bottle. 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 oromucosal spray contain 0.16 g of ketoprofen lysine salt, equal to 0.10 g of ketoprofen.
- The other ingredients are: glycerol 85%, xylitol, **methyl para-hydroxybenzoate, propyl para-hydroxybenzoate**, monobasic sodium phosphate, poloxamer, mint flavor, purified water.

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

Package containing a 15 ml bottle of solution with spray pump, cannula and dispenser.

### **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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