PATIENT INFORMATION LEAFLET

KETOBER 0.16% spray, solution

Use externally on inner lining of mouth and throat.

- ***Active substance:*** Each 1 ml solution contains 1,6 mg of ketoprofen lysinate equivalent to 1 mg ketoprofen.

- ***Excipients:*** Contains glycerin, ethyl alcohol, methyl paraben (E218), mint flavor, sodium saccharin, patent blue (E131), quinoline yellow (E104), sodium bicarbonate, polyoxyl 40 hydrogenated castor oil and deionized water.

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 questions, please ask your doctor or pharmacist.*
- *This medicine has been prescribed for you only. Do not pass it on to others.*
- *If you go to a doctor or hospital during the use of this medicine, inform your doctor about this.*
- *Follow the instructions in this leaflet exactly. Do not use **higher or lower** doses than the dose which was recommended for you.*

What is in this leaflet:

1. What KETOBER is and what it is used for?

- KETOBER is marketed in amber colored glass bottles (Type III) with a PE capillary tube immersed in the bottle and a metered-dose PP spray cap.

- These are presented in two different forms in bottles containing 15 ml and 30 ml solution in carton box.

- KETOBER contains the active substance ketoprofen lysinate, a non-steroidal anti-inflammatory and analgesic agent.

- KETOBER is indicated for the treatment of the following conditions:

- Mouth and throat conditions associated with inflammation and pain including inflammation of gums (gingivitis), oral inflammation (stomatitis), throat inflammation (pharingitis), tonsillitis or thrush (aphthous lesions)

- Prevention of growth of micro-organisms in mouth and throat, relief of swallowing function and relief of symptoms of gum disease

- Following dental procedures.

2. What you need to know before use KETOBER
DO NOT use KETOBER
If;
- You have hypersensitivity to ketoprofen or any of the ingredients in KETOBER's composition
- You have been previously diagnosed with asthma, hives (urticarial) or hay fever (rhinitis) related to use of other non-steroidal anti-inflammatory drugs

Take special care with KETOBER in the following conditions
- Prolonged use of locally administered drugs may cause sensitivity; in such a case, it is recommended to stop treatment and take appropriate medical measures.
- Methylparaben (E218) in KETOBER can cause allergic reactions (potentially delayed).

If these warnings apply to you, even if at any time in the past, please consult your doctor.

KETOBER with food and drink
There is no interaction with food and drink.

Pregnancy
Consult your doctor or pharmacist before using the medicine.
As other non-steroidal anti-inflammatory drugs, KETOBER (ketoprofen lysinate) should not be used in case of confirmed or suspected pregnancy.

Consult your doctor or pharmacist immediately if you recognize that you are pregnant during your treatment.

Breastfeeding
Consult your doctor or pharmacist before using the medicine.
Do not use KETOBER during lactation.

Driving and using machines
There is no known negative effect on driving and using machines.

Important information about some of the excipients of KETOBER
Methylparaben (E218) in KETOBER can cause allergic (potentially delayed) reactions.

This medicinal product contains less than 100 mg ethanol (alcohol) per "dose" (2-4 puffs).

The polyoxyl 40 hydrogenated castor oil content of KETOBER can cause nausea or diarrhea if swallowed accidentally; it can also cause skin reactions.

Using with other medicines
There is no known or expected interaction between KETOBER and other medicinal products. Externally (topical) administered ketoprofen has minimal systemic absorption, therefore drug interaction or other interactions are unlikely.

If you currently have been receiving or have recently received any prescription or nonprescription medicine, please notify your doctor or pharmacist about these.

3. How to use KETOBER?

- **Instructions for appropriate method and dose/frequency of administration:**

Use 2-4 puffs 3 times daily; turn up the spray pipe and place in your mouth directed at the relevant area. Spray the solution by pressing on the spray cap. Avoid swallowing.

- **Route and method of administration:**

KETOBER is only for oral topical administration.
Use KETOBER by spraying on the relevant area. DO NOT SWALLOW.

- **Different age groups:**

Use in children:
KETOBER should not be used in children as there is insufficient clinical experience.

Use in elderly:
There is no special condition for use in elderly.

- **Special conditions for use:**

Kidney/Liver failure:
The recommended dose provides 10 mg of ethyl alcohol in 0.1 ml of the solution. Therefore, it may be harmful for people with liver disease.

Although systemic exposure is minimum, it should be used with caution in patients with serious kidney impairment or serious liver impairment.

If you have the impression that the effect of KETOBER is too strong or too weak, talk to your doctor or pharmacist.

If you use more KETOBER than you should:
KETOBER overdose has no side effects since it is used on limited external area.

In case of accidental swallowing, immediately inform your doctor or go to the nearest emergency department.

If you used more KETOBER than you should, talk to a doctor or pharmacist.

If you forget to use KETOBER:

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

Effects that may occur when KETOBER treatment is stopped:
No effects occur when treatment with KETOBER is stopped.

4. Possible side effects
Local and systemic (affecting whole body) side effects were not observed associated with using ketoprofen lysinate solution.

Side effects were listed by frequency as following:
Very common: may be seen at least 1 in 10 patients.
Common: may be seen less than 1 in 10 patients but more than 1 or 1 in 100 patients
Uncommon: may be seen less than 1 in 100 patients but more than 1 or 1 in 1.000 patients
Rare: may be seen less than 1 in 1.000 patients but more than 1 or 1 in 10.000 patients
Very rare: may be seen less than 1 in 10.000 patients.
Unknown: It cannot be estimated from the available data

If any of the following occur stop using KETOBER and IMMEDIATELY inform your doctor or go to the nearest emergency department:

Unknown (cannot be estimated with the available data)

- Swelling of hands, feet, ankles, face, lips or particularly swelling of mouth or throat to cause difficulty in swallowing or breathing
- Severe skin rash
- Fainting

These are all very serious side effects.

If you get any of these, this indicates you have serious allergy to KETOBER. You may need emergency medical treatment or hospitalization.

The frequency of these very serious side effects cannot be estimated with available data.

If you notice any side effects not mentioned in this leaflet, inform your doctor or pharmacist.

5 . How to store KETOBER?

Keep KETOBER away from children's sight and reach and in its package.

Keep at room temperature below 25°C.

Use in accordance with the expiry date.
Do not use KETOBER after the expiry date indicated on the package.

Do not use KETOBER if you notice any damage on the product and/or the package

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