

PATIENT INFORMATION LEAFLET

KETOBER 1.6% Mouthwash

Externally applied to the inner surface of the mouth and throat.

- **Active substance(s):** Each 1 ml solution contains 16 mg ketoprofen lysinate equivalent to 10 mg ketoprofen.
- **Excipient(s):** Glycerin, ethyl alcohol, methyl paraben (E218), mint aroma, sodium saccharin, patent blue (E131), quinoline yellow (E104), sodium bicarbonate, polyoxyl 40 hydrogenated castor oil and deionized water.

Read this PATIENT INFORMATION 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?***
2. ***Before you use KETOBER***
3. ***How to use KETOBER?***
4. ***Possible side effects***
5. ***How to store KETOBER?***

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

- KETOBER is available in amber colored glass bottles (Type III) closed with pilfer-proof HDPE cap containing plastic seal.
- Each carton box contains one bottle containing 150 ml solution and one measuring cup with 10 ml marking.
- KETOBER contains ketoprofen lysinate which is non-steroidal and anti-inflammatory and pain killer active ingredient.
- KETOBER is used in the treatment of the following diseases:
 - In gingivitis with inflammation and pain in the mouth and throat mucosa, stomatitis, pharyngitis, tonsillitis and aphthous lesions
 - In stopping the growth of microorganisms in the mouth and throat, relieving swallowing function and eliminating symptoms in gingival disorders
 - After procedures in dentistry.

2. Before you use KETOBER

DO NOT use KETOBER in the following conditions:

If;

- you are allergic (hypersensitive) to ketoprofen or any of the other components of the KETOBER
- allergic reactions such as asthma, urticaria or rhinitis are detected in the use of other non-steroidal anti-inflammatory drugs

Use KETOBER with CAUTION in the following conditions:

- Long-term use of topical medicines may cause sensitivity, in which case treatment should be discontinued and appropriate therapeutic measures taken.

Please consult your doctor, even if these statements were applicable to you at any time in the past.

Using KETOBER with food and drink

There is no interaction with food and drinks.

Pregnancy

Ask your doctor or pharmacist for advice before using the medicine.

Like other non-steroidal anti-inflammatory drugs, KETOBER (ketoprofen lysinate) should not be used in a known or suspected pregnancy.

If you notice that you are pregnant during treatment, please consult your doctor or pharmacist immediately.

Breast-feeding

Ask your doctor or pharmacist for advice before using the medicine.

Do not use during breast-feeding.

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 may cause allergic reactions (possibly delayed).

It may cause skin reactions due to polyoxyl 40 hydrogenated castor oil contained in it.

Using with other medicines

KETOBER has no known or expected interaction with other medicinal products.

Since ketoprofen passes into the systemic circulation in very small amounts when applied externally (topical), medicines and other interactions are almost never seen.

Please tell your doctor or pharmacist if you are taking or have recently taken any other prescription or nonprescription medicine.

3. How to use KETOBER?

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

Dilute one part of the mouthwash solution (10 ml) in 100 ml of water, rinse for 20-30 seconds in the mouth and / or gargling, then spit out the remaining part; do not swallow. If not otherwise recommended by the doctor, this procedure is usually repeated 2-3 times per day.

- **Route and method of administration:**

KETOBER is for oral use only.

KETOBER is for rinsing of the mouth and/or gargling. DO NOT DRINK.

- **Different age groups:**

Use in children:

KETOBER should not be used in children because there is not enough clinical experience.

Use in elderly:

There is no specific case for use in the elderly.

- **Special Populations:**

Kidney/liver failure:

Although systemic effect is minimal, it should be used with caution in patients with severe renal or hepatic insufficiency.

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

If you used more KETOBER than you should:

Since KETOBER is used in a limited and superficial region, there is no side effect of overdose.

In the event of accidental ingestion, inform your doctor immediately or contact the emergency department of your nearest hospital.

If you may have taken more KETOBER than you should, talk to a doctor or pharmacist.

If you forget to use KETOBER:

Do not take double dose to balance the missed doses.

If you stop using KETOBER:

There is no effect when stop using KETOBER.

4. Possible side effects

There were no side effects (systemic) affecting the local (local) and whole body due to the use of the ketoprofen lysinate containing solution.

Side effects are classified according to frequency of occurrence as follows:

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 in 100 patients

Uncommon: may be seen less than 1 in 100 patients but more than 1 in 1.000 patients

Rare: may be seen less than 1 in 1.000 patients but more than 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 from the available data)

- Swelling of hands, feet, ankles, face, lips, or swelling of the throat to make it difficult to swallow or breathe
- Severe skin rash
- Syncope

These are all very serious side effects.

If you have any of them, this means you have serious allergy to KETOBER. You may need emergency medical care or hospitalization.

The frequency of these serious side effects can not be estimated from the 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 in the original package and out of the reach and sight of children.

Store at room temperature below 25°C.

Use in accordance with the expiry date.

Do not use KETOBER after the expiry date which is stated on the package.

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

Marketing authorization holder:

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