SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT
KETOBER %1.6 Mouthwash

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 1 ml solution contains

Active substance:
Ketoprofen lysinate (equivalent to 10 mg Ketoprofen) 16 mg

Excipients:
Methyl paraben 1.0 mg

For a full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM
Mouthwash

Green, clear solution with characteristic odor (mint).

4. CLINICAL PARTICULARS
4.1. Therapeutic indications
It is used in treatment of gingivitis, stomatitis, pharyngitis, tonsillitis and aphthous lesions with inflammation and pain in mouth and throat mucosa, in relieving swallowing function of the patient, in eliminating of gingival disease symptoms and after periodontal interventions.

4.2. Posology and method of administration
Posology/Frequency and duration 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.

Method of Administration:
KETOBER MOUTHWASH is only for mouthwash and / or gargling; after this process the remaining part is not swallowed and spit out.

DO NOT DRINK.

Additional information about special population:
Renal/Hepatic Failure:
There is no specific case for use in patients with renal / hepatic insufficiency.

Pediatric population:
KETOBER MOUTHWASH should not be used in children since there is not enough clinical experience.

Geriatric population:
There is no specific case for use in the geriatric population.

4.3. Contraindications
KETOBER MOUTHWASH is contraindicated in patients with hypersensitivity to the drug and in patients with allergic reactions such as asthma, urticaria or rhinitis in the use of NSAIDs

4.4. Special warnings and precautions for use
- Use only in the mouth, avoid contact with eyes and ears.
- Long-term use of topical medicines may cause sensitivity, in which case treatment should be discontinued and appropriate therapeutic measures taken
- Methylparaben in KETOBER MOUTHWASH may cause allergic reactions (possibly delayed).

4.5. Interactions with other medicinal products and other forms of interactions
No interaction has been reported with co-administration of KETOBER MOUTHWASH with other topical or systemic drugs.

4.6. Pregnancy and lactation
General recommendation
Pregnancy category: C

Women with childbearing potential / Birth control (Contraception)
Unknown.

Pregnancy
Studies on animals are insufficient in terms of effects on pregnancy / and / or / embryonal / fetal development / and / or delivery / and / or postnatal development. The potential risk for humans is unknown.
KETOBER MOUTHWASH should not be used during pregnancy unless it is necessary.

Lactation
Ketoprofen passes into breast milk. Ketoprofen is not recommended for breastfeeding mothers although the systemic absorption after topical application is low at the indicated doses.

Reproduction/Fertility
The effect on fertility is unknown.

4.7. Effects on ability to drive and use of machines
No effect on the ability to drive and use the machine.

4.8. Undesirable effects
The specified undesirable effects are classified according to the following rule:
Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1.000 to <1/100), rare (≥1/10.000 to <1/1.000); very rare (<1/10.000); not known (cannot be estimated from the available data).

Immune system disorders:
Unknown: Allergic reaction

Skin and subcutaneous tissue disorders:
Unknown: Irritation

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Turkish Pharmacovigilance Center (TÜFAM). (www.titck.gov.tr; e-mail: tufam@titck.gov.tr; tel.: 800 314 00 08; fax: 0 312 218 35 99)

4.9. Overdose
There is no overdose due to topical application. Accidental ingestion may cause systemic effects, depending on the amount ingested. In this case, supportive and indicated treatment and gastric lavage should be applied.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties
Pharmacotherapeutic group: Other Throat Preparations
ATC Code: R02AX

Ketoprofen, a non-steroidal antiinflammatory agent with analgesic and antipyretic properties, has been shown to inhibit the synthesis of prostaglandins and leukotriene and to have stabilizing effects on anti-bradykinin and lysosomal membranes.

Ketoprofen is a propionic acid derivative and a non-steroidal antiinflammatory drug with potent anti-inflammatory and analgesic effects. The lysine salt of ketoprofen is more water soluble than ketoprofen. There are inhibitory effects of ketoprofen on prostaglandin and leukotriene synthesis. It is an inhibitor of cyclooxygenase and lipoxygenase pathways. Inhibition of prostaglandin synthesis provides potent anti-inflammatory and analgesic effects. Lipoxygenase inhibitors weakens the cellular inflammation. Ketoprofen is a potent inhibitor of bradykinin (a chemical mediator of pain and inflammation), it stabilizes lysosomal membranes against osmotic damage and inhibits the release of lysosomal enzymes that cause tissue destruction in inflammatory reactions.

5.2. Pharmacokinetic properties
Absorption:
Oral topical dexketoprofen shows absorption in very small amounts.
Systemic effect is not expected due to low systemic bioavailability..
It does not accumulate in the body.

Distribution:
Following a single oral dose, the maximum blood concentration is reached within 2 hours. The plasma half-life of ketoprofen ranges from 1 to 3 hours and is bound to plasma proteins by 60-90%.

Biotransformation and elimination:
Elimination takes place essentially as glucuronide conjugates from urinary tract; approximately 90% of the administered dose is extracted within 24 hours.

Linearity/Non-linearity:
Since the effect of the product is local, the linearity between the applied dose and the systemic effect cannot be determined.

5.3. Preclinical safety data
Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Glycerin
Ethyl Alcohol
Methyl Paraben
Mint aroma
Sodium Saccharin
Patent Blue (E131)
Quinoline Yellow (E104)
Sodium Bicarbonate
Polyoxyl 40 Hydrogenated Castor Oil
Deionized water

6.2. Incompatibilities

There is no evidence that KETOBER MOUTHWASH is incompatible with any drug or substance.

6.3. Shelf life

24 months

6.4. Special precautions for storage

Store at room temperature below 25°C.

6.5. Nature and contents of container

KETOBER MOUTHWASH 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.

6.6. Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with "Directive on Control of Medical Waste" and "Directive on the Control of Packaging and Packaging Waste".

7. MARKETING AUTHORIZATION HOLDER

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8. MARKETING AUTHORIZATION NUMBER(S)

2014/608

9. DATE OF FIRST AUTHORIZATION / RENEWAL OF THE AUTHORIZATION

Date of the first authorization: 06.08.2014
Date of the renewal of the authorization: 23.01.2020

10. DATE OF REVISION OF THE TEXT

10.08.2016