SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

KETOBER 0.16% spray, solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml of the solution contains:
Active substance:
1.6 mg ketoprofen lysinate equivalent to 1 mg ketoprofen.

Excipients:

Methyl paraben (E218)	1 mg
Ethyl alcohol	100 mg
polyoxyl 40 hydrogenated castor oil	1,55 mg

See 6.1 for excipients.

3. PHARMACEUTICAL FORM

Spray

Green colored, clear solution with characteristic (mint) odor.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Indicated in conditions of oral and pharyngeal mucosa associated with inflammation and pain including gingivitis, stomatitis, pharyngitis, tonsillitis and aphteous lesions, for relief of swallowing functions and symptomatic treatment of gum disorders, following periodontal procedures.

4.2 Posology and method of administration

Posology/frequency and duration of administration:
Three times a day, 2-4 puffs
Each puff provides 0.1 ml of solution equal to 0.16 mg of the active substance.
Caution: Do not exceed the indicated dosage.

Consult a doctor if the condition persists or if any change in the type of the condition occurs.
Caution: Use only for short treatment periods.

Mode of administration:
Turn up the cannula and place in your mouth with the spray pipe directed at the relevant area. Spray the solution by pressing on the spray cap. Avoid swallowing.

Additional information on special populations:
Renal impairment:
There is no special condition for use in patients with renal impairment.

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

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

Geriatric population:
There is no special condition for use in the geriatric population.

4.3. Contraindications
KETOBER is contraindicated in patients with known hypersensitivity to ketoprofen or any of its components.

KETOBER is contraindicated in patients with advanced asthma and in patients with a history of asthma attacks, bronchospasm, allergic rhinitis, urticarial or angioneurotic edema associated with use of other non-steroidal anti-inflammatory drugs.

4.4. Special warnings and precautions for use
KETOBER is administered by spraying on the relevant area in the mouth; it should not be swallowed.

- 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 (potentially delayed) reactions.
- This medicinal product contains less than 100 mg of 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.

4.5. Interactions with other medicinal products and other forms of interaction
No interactions were reported for concomitant use of KETOBER and topical or systemic drugs.

Additional information on special populations:
No interaction studies associated with special populations have been conducted.

Pediatric population:
No interaction studies were conducted on pediatric population.

4.6. Pregnancy and lactation
General recommendation
Pregnancy category: C

Women of child-bearing potential/ Birth control (Contraception)
Unknown.

Pregnancy
Animal studies are insufficient in terms of effects on pregnancy and/or embryonal/fetal development and/or labor and/or post-partum development. The potential risk for humans is unknown.
KETOBER should not be used while planning a pregnancy or during pregnancy.

Lactation
Ketoprofen passes into the breast milk. Although minimal systemic exposure occurs following topical administration of the indicated doses, ketoprofen use is not recommended for breastfeeding mothers.

Reproduction / Fertility
Effect on reproduction is unknown.

4.7. Effects on ability to drive and use machines
No effects of KETOBER on the ability to drive and use machines have been observed.

4.8. Undesirable effects
The undesirable effects were classified based on the following descriptions:

Very common (>1/10); common (>1/100 to <1/10); uncommon (>1/1.000 to <1/100); rare (>1/10.000 ila <1/1.000); very rare (<1/10.000), unknown (cannot be estimated from the available data).

Immune system disorders
Unknown: Allergic reaction (angioneurotic edema)

Skin and subcutaneous tissue disorders
Unknown: Irritation

4.9. Overdose and management
Although cases of overdosing were not seen, accidental overdose should be avoided considering the amount of active substance.
In case of accidental swallowing/administration of KETOBER overdose, supportive and symptomatic treatment and gastric lavage should be performed.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties
Pharmacotherapeutic group: Other throat preparations
ATC Code: R02AX

Ketoprofen, which is a non-steroidal anti-inflammatory agent with analgesic and antipyretic properties, was shown to inhibit synthesis of prostaglandins and leukotrienes and also have anti-bradykinin and lysosomal membrane stabilizing effects.

Ketoprofen is a propionic acid derivative non-steroidal anti-inflammatory agent with strong anti-inflammatory and analgesic effects. Ketoprofen lysine salt is more soluble in water compared to ketoprofen. Ketoprofen has inhibitory effects on prostaglandin and leukotriene synthesis. It is an inhibitor of cyclooxygenase and lipoxygenase pathways. Inhibition of prostaglandin synthesis provides strong anti-inflammatory and analgesic activity. Lipoxygenase inhibitors reduce cell-based inflammation. Ketoprofen is a strong inhibitor of bradykinin (chemical mediator for pain and inflammation), provides lysosomal membrane stabilization against osmotic damage and inhibits release of lysosomal enzymes that cause tissue damage during inflammatory reactions.

5.2. Pharmacokinetic properties

Absorption:

Intraoral topically administered dexketoprofen is minimally absorbed.
Systemic effects are not expected due to low systemic bioavailability.
Does not accumulate in the body.

Distribution:

After single oral dosing, maximum blood concentrations were achieved within 2 hours. The plasma half-life of ketoprofen ranges between 1 to 3 hours; it is 60-90% bound to plasma proteins.

Biotransformation and Elimination:

Elimination occurs primarily by urinary route and through glucuronate conjugates; approximately 90% of the administered dose is eliminated within 24 hours.

Linearity/non-linearity:

Given the product has local effects, linearity between the administered dose and systemic activity cannot be established.

5.3. Preclinical safety data

Not reported.

6. PHARMACEUTICAL PARTICULARS

6.1. List of the excipients

Glycerin
Ethyl alcohol
Methyl paraben (E218)
Mint flavor
Sodium saccharin
Patent blue (E131)
Quinoline yellow (E104)
Sodium bicarbonate
Polyoxyl 40 hydrogenated castor oil
Purified water

6.2. Incompatibilities

There is no evidence indicating incompatibility of KETOBER with any drug or substance.

6.3. Shelf life

24 months

6.4 Special precautions for storage

Keep at room temperature below 25 °C.

6.5. Nature and contents of the container

KETOBER is available 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.

6.6. Special precautions for disposal and other handling

Unused products and waste material should be discarded in accordance with “Medical Waste Control Regulations” and “Packaging and Packaging Waste Control Regulations”.

7. MARKETING AUTHORIZATION HOLDER

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8. MARKETING AUTHORIZATION NUMBER

2014/908

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 19.12.2014
Date of the renewal of the authorization:

10. DATE OF REVISION OF SPC

03.05.2019