Orofar®

With lidocaine

Lozenges, gelsolets, buccal spray, solution
Inflammatory conditions of the oropharynx

Composition
1 *lozenge* contains:
Active principles: Benzoxonii chloridum 1 mg, Lidocaini hydrocloridum 1 mg. Excipients: Sorbitolum 1 g, Saccharinum, Aromatica.
One lozenge contains 1 g sorbitol sweetener, corresponding to approx. 17 kJ (4 kcal). The lozenges are orange flavoured.
Information for diabetics: 10 tablets are equivalent to one ration of fruit.

1 *gelsolet* contains:
Active principles: Benzoxonii chloridum 1 mg, Lidocaini hydrochloridum 1 mg. Excipients: Levomentholum, Eucalypti aetheroleum, Menthae piperitae aetheroleum, Saccharinum.

1 ml of *buccal spray* contains:
Active principles: Benzoxonii chloridum 2 mg, Lidocaini hydrochloridum 1.5 mg. Excipients: Ethanolum 12,4% v/v, Menthae piperitae aetheroleum, Levomentholum.

10 ml *solution* contain:
Active principles: Benzoxonii chloridum 5 mg, Lidocaini hydrochloridum 5 mg. Excipients: Ethanolum 12,4% v/v, Menthae piperitae aetheroleum, Levomentholum.

Properties/Effects
Benzoxonium chloride has a bactericidal activity in vitro against Gram-positive and, to a lesser degree, Gram-negative organisms. It also has a fungicidal and antiviral activity against membrane viruses such as the influenza, parainfluenza and herpes hominis viruses. The cationic structure of benzoxonium chloride confers high surface activity and hence good penetration. Several clinical trials have shown that Orofar is effective in the treatment of sore throat, and also gingivitis through its ability to inhibit the formation of dental plaque.
Lidocaine is a local anaesthetic which soothes sore throat and pain on swallowing caused by inflammation.
Orofar does not promote caries: the lozenge are sweetened with sorbitol and saccharine and the gelsolets with saccharine.

Pharmacokinetics
Benzoxonium chloride is almost completely unabsorbed.
In man, approximately 1% of the administered dose is found in the urine, and blood concentrations are virtually undetectable. These findings are similar to those in animals, in which approximately 95% of an oral dose is eliminated in the faeces. Tissue accumulation is not observed.
Lidocaine is absorbed after oral administration or through the buccal mucosa. It undergoes first-pass elimination in the liver, and bioavailability is approximately 35% following oral administration. Lidocaine is rapidly metabolized in the liver, and the metabolites are eliminated in the urine, with less than 10% being excreted unchanged.

Indications/Method of use
Oropharygeal infection (local disinfectant and analgesic activity): pharyngitis, laryngitis, sore throat in case of cold, stomatitis, ulceration, gingivitis. Adjuvant in case of tonsilitis.

Dosage/Directions for use
Lozenges, gelsolets: Mild infections: 1 lozenge/gelsolet every 2–3 hours. Acute infections: 1 lozenge/gelsolet every 1–2 hours. Let the gelsolet or lozenge dissolve slowly in the mouth. Ulceration: melt the gelsolet against the lesion. Do not exceed a dose of 10 lozenges or gelsolets daily.

Buccal spray: Orofar spray is for oromucosal use only (mouth and throat). Do not use the actuator if it is damaged. 3–6 applications daily. Apply Orofar spray in the mouth or the back of the mouth three to six times a day. Hold the spray upright and spray four times during each application.

Before you use Orofar spray:
– Remove the protecting cap
– Apply the actuator on the top of the pump by pressing firmly. Before the first use, prime the pump by pressing the actuator a few times until one spray is released in the air.
– The actuator should be disinfected after use with a clean tissue moistened with a small amount of Orofar® solution and then dried. In particular, it should be disinfected and dried before use by another person.
– The actuator should be removed after use and store in the folding box of Orofar® spray medicinal product until further use.

This dose is equivalent to approximately 0.5 ml and contains the same amount of active principle as one lozenge or gelsolet.

Solution: Rinse the mouth or gargle for 30–60 seconds morning and night after meals with 15–20 ml (one soupspoon) of neat solution. If continuous treatment is indicated, the solution can be used more frequently or replaced with lozenges, gelsolets or spray during the day.

Children: Orofar can be administered to children aged 4 years and over, but at slightly lower doses: do not exceed 6 lozenges or gelsolets daily, activate the spray only 2 or 3 times at each application, and rinse or gargle with only one dessertspoonful of solution (10–15 ml).

Restrictions on use
Contraindications
Hypersensitivity to quaternary ammonium compounds or lidocaine.

Precautions
Not recommended for children below the age of 4.

Pregnancy/Breast feeding
No adverse foetal effects have been observed in animal reproduction studies, but there have been no controlled trials in pregnant women. Orofar should therefore not be used during pregnancy, particularly during the first trimester. In the absence of available data on elimination of the active principles in breast milk, Orofar should not be used when breastfeeding.

Undesirable side effects
Transient mild local irritation may sometimes occur. Allergic skin reactions are rare.
A reversible brown coloration may appear on the tongue and/or teeth when Orofar solution is used for more than two weeks.

Interactions
As with all quaternary ammonium compounds, the efficacy of benzoxonium chloride present in Orofar can be diminished by simultaneous use of anionic tensioactive agents, e.g. toothpastes.

Overdosage
Accidental ingestion of a large amount of Orofar, as of any quaternary ammonium compound, may cause nausea or vomiting. Milk or egg white beaten in water should be administered immediately. Alcohol enhances absorption and should be avoided.
The concentration of lidocaine in the various formulations of Orofar are too low to cause symptoms if overdosage occurs.

General remarks
Storage
Medecines should be kept out of reach of children.
Lozenges, gelsolets: protect from moisture and heat.
Do not store above 30 °C.
Buccal spray, solution. Do not store above 30 °C.
The product may be used up to the day ‹EXP› shown on the pack.

Packaging
Lozenges: pack of 24 lozenges.
Gelsolets: pack of 24 gelsolets.
Buccal spray: pack of 30 ml.
Solution: pack of 200 ml.

Novartis Consumer Health SA Nyon Switzerland

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NOVARTIS

(THIS IS A MEDICAMENT)

a. Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
b. Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold the medicament.
c. The doctor and the pharmacist are experts in medicine, its benefits and risks.
d. Do not by yourself interrupt the period of treatment prescribed.
e. Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists

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