Orofar®

0.2% Buccal Spray
Patient Information Leaflet (PIL)
For oromucosal use only (mouth and throat).
Each 1 ml of Orofar Buccal Spray 0.2% contains (active ingredients) 2mg benzoxonium chloride, 1.5mg lidocaine hydrochloride
Excipients: Ethanol (96%), Flavourings: Glycerol, hydrochloric acid 0.1 N (for pH-adjustment), Peppermint oil, Levomenthol, purified water.
Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.
– Keep this leaflet. You may need to read it again.
– Ask your pharmacist if you need more information or advice.
– If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
– You must talk to a doctor if you do not feel better or if you feel worse after 5 days.

In this leaflet

1. What is Orofar Buccal Spray and when is it used?
Orofar buccal Spray relieves the symptoms of infections in the oral and pharyngeal cavity (local disinfectant and analgesic effect): Associated with Pharyngitis, laryngitis, sore throat with the common cold, stomatitis, aphthae, gingivitis
Orofar contains a disinfectant (benzoxonium chloride) and a local pain-relieving drug (lidocaine hydrochloride). Lidocaine, a local anaesthetic, relieves sore throat and swallowing difficulties caused by infection.
Orofar buccal spray has an antibacterial, antiviral and antifungal effect.
Supportive treatment for tonsillitis.

2. How to use Orofar Buccal Spray?
Always use this medicine as described in this leaflet or as your doctor or pharmacist has told you.
– Orofar spray is for Oromucosal use only (mouth and throat).
– Do not exceed the stated dose
– Speak to your doctor or pharmacist if you believe the medication is acting too weakly or strongly

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.
– Hold the bottle upright and spray in the mouth or the back of the mouth. Hold breath while spraying.
– Clean and dry the actuator after use and store it in the folding box until further use.
– To avoid possible spread of infections, the actuator should only be used by one person.
– Do not use the product if the actuator is damaged.
– The actuator should be removed after use and store in the folding box of Orofar® spray medicinal product until further use.

Dose For Children 4-11 years:
Unless otherwise prescribed by your doctor
– The dose is 2 or 3 sprays in the mouth or back of the mouth on the affected area.
– The dose can be repeated 3 to 6 times a day as needed, leaving an interval of at least 2 to 3 hours between each dose.
– The spray should be used in children only under adult supervision
– It should not be used in children who are unable to hold their breath whilst spraying.

Dose For Adults and children over 12 years:
Unless otherwise prescribed by your doctor
– The dose is 2 to 4 sprays in the mouth or back of the mouth on the infected area.
– The dose can be repeated 3 to 6 times a day as needed, leaving an interval of at least 2 to 3 hours between each dose.

* Orofar should not be used in children under 4 years of age
* There is no need for dose reduction in the elderly

3. What you need to know before using Orofar Buccal Spray?
a. Do Not Use Orofar Buccal Spray if you are allergic (hypersensitive) to:
– benzoxonium chloride or other quaternary ammonium compounds,
– any of the other ingredients of this medicine listed above
– lidocaine hydrochloride or other amide local anaesthetics

b. Warnings and precautions
Talk to your doctor or Pharmacist before using Orofar Buccal Spray
– If the sore throat is accompanied by a high fever, if there are severe difficulties swallowing
– If the symptoms do not improve or persist for more than 5 days.
– Children under the age of 4 years should not be given Orofar Spray
– Orofar is only intended for use in the mouth and throat. Do not spray in the eye and do not inhale. (Hold breath while spraying)
– The throat spray nozzle should not be used if it is damaged.
– Orofar Spray should be used only with caution in case of wounds and injuries of the oral and laryngeal mucosa.
– Orofar spray should not be used while eating or drinking or immediately afterward. The local anaesthetic effect of lidocaine may cause temporary numbness of the tongue and oral mucosa and therefore impair swallowing. Do not eat or drink anything for as long as the numbness persists.
– Orofar should not be used immediately before or after brushing teeth as this reduces its effectiveness.
– Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines. If you are suffering from other diseases or having any allergies.
– This medicinal product contains small amounts of ethanol (alcohol), less than 100 mg per dose (one spray actuation delivers 140 microliter ± 25%, containing 13.132 mg ± 25% of ethanol and the maximum dose at one time is 4 sprays).

c. Taking Other Medications with Orofar Spray
Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.
Interaction studies have not been carried out.
Benzoxonium chloride:
No interaction is to be expected with benzoxonium chloride due to its very low systemic absorption.
Lidocaine:
Lidocaine may theoretically interact with other medicines administered concomitantly, e.g. with other anti-arrhythmic agents. No drug interactions are to be expected, since it is administered only in very small quantities.

d .Pregnancy, Breast-feeding, and Fertility
If you are pregnant or breastfeeding, if you suspect that you are pregnant or plan to become pregnant, then you should not use medicinal products to be on the safe side or ask your doctor, pharmacist or druggist for advice.

Pregnancy
Experimental animal studies with benzoxonium chloride and lidocaine hydrochloride, administered individually or as mixture, have not indicated a teratogenic potential nor a negative effect on the embryonic or foetal development.
There are however no controlled studies in pregnant women.
Accordingly, the use of Orofar Spray should be avoided during pregnancy, especially during the first trimester.

Breast feeding
Benzoxonium chloride:
It is not known whether benzoxonium chloride is excreted into breast milk, however, the levels available to the infant would be negligible due to poor absorption and very low bioavailability of the drug.
Lidocaine:
Small amounts of lidocaine are excreted into breast milk but potential harm to the infant is considered to be unlikely at therapeutic dose levels. Orofar Spray should not be used while breastfeeding.

Fertility
No data on human fertility is available. Animal reproductive toxicity studies conducted with benzoxonium chloride and lidocaine individually and/or in combination have not shown any adverse effects on fertility.

e. Driving and using machines
Orofar has no or negligible influence on the ability to drive and use machines.

4. Possible side effects:
Like all medicines, this medicine can cause side effects, although not everybody gets them.
STOP using Orofar and seek medical help immediately if you notice any of the following which may be signs of an allergic reaction:
- difficulty in breathing or swallowing
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps

Some side effects are common: Irritation or tingling in the mouth and throat.
If Orofar Spray is used for more than two weeks, the tongue and / or teeth can turn brown, but this is reversible. If you notice any side effects not listed in this leaflet, please tell your doctor, pharmacist or chemist
Adverse reactions are listed below by system organ class and frequency. Frequencies are defined as: 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), or not known (can not to be estimated from available data). Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

Immune System
Very Rare: Hypersensitivity reactions (including facial, lip, tongue and laryngeal oedema).

Respiratory system
Very Rare: Dyspnoea.

Intestinal tract
Common: Symptoms in the area of the mouth, Oral discomfort

Skin
Very Rare: Rash, itching.

Reactions at the site of application
Rarely: A reversible brown discolouration of the tongue and/or teeth can occur if used longer than 2 weeks.
Pediatric population
Frequency type and severity of adverse reactions in children are expected to be same as in adults.

5. Overdose
Benzoxonium chloride
As with all quaternary ammonium compounds, accidental ingestion of a large quantity of benzoxonium chloride may cause nausea or vomiting. Treatment of poisoning is symptomatic, demulcents should be given if necessary but emesis and lavage should be avoided. Immediate administration of milk or egg whites beaten in water is recommended. Avoid alcohol as it promotes absorption.

Lidocaine
Lidocaine intoxication is mainly due to inadvertent intravenous overdose and has serious effects on central nervous system (CNS) and cardiovascular systems, such as hypotension, asystole, bradycardia, apnea, seizures, coma, cardiac arrest, respiratory arrest, and death. Overdose due to oral administration of topical solutions is less likely because of the large quantities of solutions required to be ingested and because of the extensive first pass metabolism of lidocaine. Although the bioavailability of lidocaine from oral administration is low, it may result in significant toxicity when swallowed and there have been reports of CNS effects, such as seizures and deaths in children and adults after ingestion of viscous solutions of lidocaine, as well as gargling with a 4% lidocaine solution. Treatment of lidocaine intoxication is symptomatic and consists in controlling cardiovascular and respiratory functions as well as convulsions.
All patients who have ingested accidentally or deliberately large quantities of Orofar with lidocaine should be referred immediately to a physician for medical assessment or contact a poison control center.

6. How to store Orofar Buccal Spray?
Do not store above 30°C.
This medicine must not be used beyond the date indicated after expiry date "EXP" on the container.
Sore in the Original package
Keep out of the reach and sight of children.

7. Contents of the Pack and other Information:
Orofar Buccal spray is a colorless, clear solution in a 30ml Pack

NOVARTIS

Manufactured by:
Novartis Consumer Health SA
Nyon, Switzerland

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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 the experts in medicines, their benefits and their 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