

OXACAIN (Lidocaine 10% Oromucosal Spray)

Composition:

Each 1 ml of OXACAIN (Lidocaine 10% Oromucosal Spray) contains:

Active ingredient: Lidocaine 100 mg

Excipients:

Ethanol, Propylene glycol, Soluble banana essence, l-Menthol, Neotame, Purified water

Product Description:

Clear glass bottle (type I) (50 mL) with metering spray pump and a polyethylene/polypropylene dip tube which is crimped onto the neck of the bottle. The pump assembly is protected by a white propylene overcap.

The propylene nozzle actuator is supplied separately inside the carton and replaces the overcap prior to use.

The bottle contains clear, colorless to slightly yellow-coloured solution with menthol and banana flavor

Properties:

OXACAIN (lidocaine) is a safe and effective local anesthetic, belonging to the amide class of local anesthetics for surface anesthesia of oral mucous membrane.

Action:

Following local application of OXACAIN oromucosal spray, lidocaine penetrates oral mucous membrane altering cell membrane permeability of ions particularly sodium influx and preventing initiation and conduction of nerve impulses. Clinically, OXACAIN oromucosal spray provides prompt and profound local anesthesia that appears within 1 - 5 minutes post application to mucous membrane and lasts for about 15 - 30 minutes.

This is beneficial in instantaneous relief of pain associated with dental practice or before otorhinolaryngology. Also, OXACAIN action facilitates insertion of instruments during endotracheal intubation and endoscopic procedures of the airways and upper GIT. OXACAIN oromucosal spray is free of propellant gases and easy to handle besides high safety profile which recommends its use in all disciplines requiring oral mucous membrane surface anesthesia.

Pharmacokinetics:

Following application of OXACAIN oromucosal spray, absorption of lidocaine from mucous membrane depends upon concentration, total dose administered, the specific site of application and duration of exposure. About 64% of the absorbed lidocaine is bound to plasma proteins. Lidocaine is metabolized rapidly by the liver and excreted in the urine as metabolites and as unchanged drug.

Indications:

OXACAIN oromucosal spray is indicated in surface anesthesia:

- Before injections in dental practice, dental impressions (especially copperband impression), X-ray photography, removal of calculus.
- Before puncture of the maxillary sinus and surgical procedures in the nasal cavity, pharynx and epipharynx paracentesis.

Dosage and Mode of Administration:**Route of administration:** Oropharyngeal.

- In dental practice: 1-5 applications to oral mucous membranes. Onset of action is within 1-2 minutes.
- Puncture of the maxillary sinus and other otorhinolaryngology procedures: 3 applications. Onset of action is within 2-3 minutes.

Contraindications:

Hypersensitivity to lidocaine or any component of the oromucosal spray. Lidocaine must not be used on open wounds or infected areas (local sepsis).

Warning and Precautions:

Local anesthetics must not be applied for prolonged periods or over large areas of mucous membranes or sprayed near or into the eyes. OXACAIN oromucosal spray must not be used by patients having allergy to local anesthetics and patients having epilepsy or liver, heart or kidney problems.

Side Effects:

Local adverse reactions might occur with applied lidocaine and include allergic reactions or drowsiness. Other side effects that may rarely occur include dizziness, blurred vision, tremors, nervousness, wheezing or difficulty in breathing, chest pain, severe rash or itching and increased sweating.

Pregnancy and Lactation:

No harmful effects have been reported on the use of local anesthetics during pregnancy and lactation. However, OXACAIN oromucosal spray should be used during pregnancy under strict medical supervision.

Drug Interactions:

- OXACAIN should be used with caution in patients receiving class I antiarrhythmic drugs (such as tocainide and mexiletine) since the toxic effects are additive and potentially synergistic.
- When OXACAIN is used concomitantly with other products containing local anesthetic agents, the amount absorbed from all formulations must be considered.

Interference with Laboratory Tests: None reported with local anesthetics.

Overdosage and Treatment:

Symptoms of overdosage include drowsiness, confusion, nervousness, ringing in ears, blurred vision, feeling hot or cold, numbness, muscle twitches, slowed breathing or respiratory failure. Treatment is symptomatic and supportive.

Storage conditions:

Do not store above 30° C. Store in original package to protect from light.

Manufactured by:

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