Physicians' Prescribing Information

HURRICAINE®

Topical Anesthetic Gel for Oral Use
20% Benzocaine Oral Anesthetic

1. Name of the medicinal product: HURRICAINE

2. Qualitative and quantitative composition: Benzocaine 20% w/w
For full list of excipients, see Section 6.1.

3. Pharmaceutical form: Gel for oral use (dental gel)

4. Clinical particulars
4.1 Therapeutic indications: HURRICAINE is designated for any dental procedure in which topical anesthesia is desired. HURRICAINE is also used for temporary relief of occasional minor irritation and pain associated with: canker sores, sore mouth and throat, minor injury of the mouth and gums caused by dentures or orthodentic appliances.

4.2 Posology and method of administration: Adults and children aged 12 years and over.
Directions: • Spit out, swallow or vacuum excess saliva from mouth • With a clean finger or swab apply an amount of gel the size of a green pea into the tooth cavity or to the affected area, to form a thin film • Allow to remain in place at least 1 minute and then spit out • Do not re-use or re-dip in the gel the finger or swab once placed in mouth. This will prevent cross-contamination of the gel • Use up to 4 times daily. Do not exceed recommended dosage • Do not use continuously. If toothache persists, consult your dentist.

Not for use in children below the age of 12 years.

HURRICAINE is designed for rapid onset (10-30 seconds). Anesthesia usually lasts 8-10 minutes. Benzocaine has been shown to be a safe, effective anesthetic with little or no systemic absorption.

4.3 Contraindications: Known sensitivity to benzocaine or any of the other ingredients.
Not to be used in those individuals suspected of lacking the normal ability to convert methaemoglobin to haemoglobin, see Section 4.4 Special warnings and precautions for use and Section 4.8 Undesirable effects.
Not for use in children below the age of 12 years.
HURRICAINE is not for injection. Avoid contact with eyes.

4.4 Special warnings and precautions for use: Do not use if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics.
HURRICAINE is intended for short-term use until a dentist can be consulted. Do not use continuously. Do not exceed recommended dose.
Do not use if you have a family history of methaemoglobinaemia
Patient should be advised to consult a doctor if sore mouth symptoms do not improve in 7 days.
Patient should wait some time after using this product before eating any food, due to possible interruption to swallowing. Likewise, do not chew food or gum, as long as the area is numbed. Avoid drinking hot liquids whilst using HURRICAINE.

4.5 Interaction with other medicinal products and other forms of interaction: Benzocaine, like other derivatives of para-aminobenzoic acid, inhibits the actions of sulphonamides and therefore should not be used concomitantly with any sulphonamide.

4.6 Pregnancy and lactation: There is inadequate evidence of safety of benzocaine in human pregnancy, but it has been in wide use for many years without apparent ill consequences. No clinical data are available on the use of this product during pregnancy and lactation.
Therefore it should not be used in pregnancy or lactation unless considered essential by a physician.

4.7 Effects on ability to drive and use machines: No effect on subjects' ability to drive or operate machines.

4.8 Undesirable effects: Application of benzocaine on skin and mucous membranes has resulted in hypersensitivity reactions (burning, stinging, pruritis, erythema, rash and edema), contact dermatitis and methaemoglobinaemia in a few cases in infants, children and adults. If symptoms persist, or are severe, or are accompanied by fever, headache, breathlessness, nausea and vomiting, consult a doctor.

4.9 Overdose: Excessive absorption of benzocaine may produce methaemoglobinaemia in infants, children, and adults. The first clinical signs are cyanotic (greyish) skin discolouration (most notably on mucous membranes) and signs of unusual breathing or breathlessness.
Methaemoglobinaemia may be treated by the intravenous administration of 1% methylene blue. Treatment of overdose should be symptomatic and supportive.

Benzocaine overdose: The primary toxic effect following benzocaine exposure is methemoglobinemia. Tachycardia, hypotension, hyperpnea, cyanosis, lethargy, and metabolic acidosis may occur secondary to significant methemoglobinemia (greater than 40%).
Adverse effects: gastro-Intestinal (GI) irritation may occur with ingestion. Contact dermatitis can develop following topical application of benzocaine.
Onset: onset of methemoglobinemia usually occurs within 20 to 60 minutes of exposure.
Treatment: 1) Decontamination: Consider activated charcoal soon after large ingestions (topical preparations are absorbed rapidly). 2) Support: Treatment is symptomatic and supportive. 3) Methemoglobinemia: Methylene blue 1 to 2 mg/kg/dose IV over 5 minutes as needed every 4 hours. It is contraindicated in patients with G6PD deficiency. Hyperbaric oxygen as an adjunct therapy in very severe cases, exchange transfusion may be considered if unresponsive to methylene blue.
Range of Toxicity: Adults: Severe methemoglobinemia has occurred after 3 or 4 one-second sprays with 20% benzocaine. Caution: Severe methemoglobinemia may develop in some individuals (particularly G6PD or NADPH-dependent methemoglobin reductase deficient individuals) at low doses. Therapeutic: Adult: Apply topically to affected areas up to 4 times daily. Children (aged 12 years and older): Apply topically to affected areas up to 4 times daily.

5. Pharmacological properties
5.1 Pharmacodynamic properties: Pharmacotherapeutic group: Local anaesthetics, ATC code: N01BA05
Benzocaine is a local anaesthetic of the ester type with rapid onset, acting to produce reversible loss of sensation by preventing or diminishing the generation and transmission of sensory nerve impulses near the site of application. Depolarisation of the neuronal membrane and ion exchange are reversibly inhibited.

5.2 Pharmacokinetic properties: Benzocaine is absorbed through mucous membranes and damaged skin. Anaesthetics of the ester type are hydrolysed by esterases in the plasma and, to a lesser extent, in the liver.
Benzocaine is sparingly soluble in water with toxicity about a tenth that of cocaine. It is an ester which on hydrolysis produced p-aminobenzoic acid.

5.3 Preclinical safety data: There are no additional pre-clinical data of relevance to the prescriber.

6. Pharmaceutical particulars
6.1 List of excipients: Polyethylene Glycol 400, Polyethylene Glycol 3350, Fritzbro Artificial Wild Cherry Flavor, Sodium Saccharin.
Special flavoring and sweetening agents are incorporated to render flavors of superior taste (with no after taste).

6.2 Incompatibilities: Not applicable.

6.3 Shelf life: The expiry date of the product is indicated on the label and packaging. Do not use after the expiry date.

6.4 Special precautions for storage: Store in a cool place (below 25°C). Keep all drugs out of reach of children.
In-use shelf life: use within 3 months after first opening.

6.5 Nature and contents of container: Plastic bottle with screw cap, containing 28.35 gram of gel. Plastic tube with dispenser tip closed with a screw cap, containing 5.25 gram of gel. Other pack forms and pack sizes might be available.

6.6 Special precautions for disposal and other handling: Not applicable.

6.7 Israeli Drug Registration Number: 142.11.32950.00

6.8 Manufacturer: Beutlich Pharmaceuticals, LLC, Bunnell, Florida 32110, USA (together with Dental Technologies, Lincolnwood, Illinois 60712, USA)

6.9 Israeli Marketing Authorization Holder: A. Levy Dental Co. Ltd., VAT# 510917768, 27 Kalisher Street, Tel Aviv 65165

The format of this leaflet was decided by the Israeli Ministry of Health and its contents was checked and approved by them on date: 09/2014