	PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986
–	The medicine is dispensed without a doctor's prescription
HUR	RICAINE
Gel for	Oral Use
1) NAME	OF THE MEDICINE, ITS FORM AND STRENGTH:
-	the medicine: Hurricaine
Form: Gel	for oral use
	e ingredient and its concentration per dosage unit: Benzocaine 20% w/w of inactive and allergenic ingredients in the medicine - see section 6.
This leafle questions, The medic manner. C	<b>leaflet carefully in its entirety before using the medicine.</b> et contains concise information about the medicine. If you have further, refer to the doctor or pharmacist. ine is intended for both men and women. Use the medicine in the correct onsult the pharmacist if you need further information. he dentist or doctor if the symptoms worsen or do not improve after the symptoms.
What is th	ne medicine intended for?
	rine provides topical oral anesthesia, when a medical procedure has to be I in the mouth.
The medic mouth, as • Mouth u	cine provides temporary relief in cases of pains or minor irritation in the sociated with cases of: lcers
	buth and throat nage in the oral cavity and on the gums caused by use of dentures or othe ices.
Therapeu	tic group: local anesthetic.
2) BEFOF	RE USING THE MEDICINE:
1 and t manifes - if you o	ents contained in the medicine. The active ingredient is mentioned in section he inactive ingredients are listed in section 6. An allergic reaction can be sted by appearance of a rash, itching, swelling or burning. r your relatives suffer from methemoglobinemia. ren below the age of 12.
<ul> <li>Refer to days.</li> <li>If you are the med</li> <li>Do not to</li> </ul>	use the medicine if you have a history of an allergic reaction to topica tics, such as: procaine, butacaine, and other topical anesthetics from the
H If you ar suppleme doctor or j	e taking other medicines, including non-prescription medicines or dietary ints, tell the dentist, doctor or pharmacist. In particular, inform the dentist pharmacist if you are taking one or more of the following medicines: amides, e.g., antibiotics such as : sulphamethoxazole, co-trimoxazole.
Use of to oral anesthof food. D	<b>he medicine and food:</b> After using the medicine, avoid eating food until the netic effect has worn off, due to fear that the medicine will disturb swallowing o not chew food (including gum) while the topical oral anesthetic effect o ine is still apparent. Avoid drinking hot drinks.
	he medicine during pregnancy or when breastfeeding: If you are pregnan eeding, do not use the medicine without consulting a dentist or doctor.
•	and operating machinery sine has no effect on ability to drive and/or operate machinery.
,	SHOULD YOU USE THE MEDICINE? e according to the instructions. Check with the dentist, doctor or pharmacis uncertain.
Recomme dose is ge instruction The medic The medic	ended dosage for adults and adolescents ages 12 and over: The usual nerally application of the gel up to 4 times a day, unless you received othe of from the dentist or doctor. Do not exceed the recommended dosage. sine is not intended for children below the age of 12. sine is characterized by a rapid onset of action – the anesthesia will set in 30 seconds.
Instructio	ns for use of the medicine:

#### Instructions before using the medicine:

- Clean your mouth from saliva by spitting it out or swallowing it.
- Open the cap, slice or cut the tip of the tube close to the elongated tip, to generate a small slit, and press on the body of the tube to release the gel onto a clean finger or onto a new swab.
- Be sure to place the required amount of gel on the tip of the swab/finger, which is usually the size of a pea.
- Apply the gel, that is on the finger or tip of the swab, onto the required area in the mouth.
- <u>After your finger has touched your mouth</u>: If more gel has to be applied inside the mouth, wash the finger with water and soap before removing an additional amount of gel out of the package. This will prevent possible contamination of the rest of the gel in the package.
- <u>After the swab was used inside the mouth</u>: if more gel has to be applied inside the mouth, do not use the same swab again. Use a new swab. This will prevent possible contamination of the rest of the gel in the package.
- **Duration of treatment with the medicine:** If there is no improvement of your condition after 7 days, refer to a dentist or doctor.
- Avoid contact between the gel and eyes. In case of contact with the eyes, wash the eyes immediately with running water for a few minutes. If necessary, call the dentist, doctor or pharmacist immediately.
- If you took an overdose or if a child has accidentally swallowed the medicine, immediately refer to a dentist, doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.
- If you forget to take this medicine at the required time, do not take a double dose.
   Take the next dose at the scheduled time and consult the dentist or doctor. If you accidentally took a double dose, call the dentist, doctor or pharmacist immediately.

How can you contribute to the success of the treatment? Do not take medicines in the dark! Check the label and the dose <u>each time</u> you take the medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the dentist, doctor or pharmacist.

#### 4) SIDE EFFECTS:

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у t, As with any medicine, the use of this medicine may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

## Stop using the medicine and refer to a dentist or doctor immediately if you feel or suffer from:

Irritation, local rash or inflammation (that did not exist before using the medicine).

Extraordinary weakness, dizziness, breathing difficulties, cyanosis (very rare, and common at young ages) – these may be signs of methemoglobinemia – increased blood methemoglobin levels. Stop treatment with the medicine and <u>immediately proceed</u> to an emergency room.

If one of the side effects worsens, or if you are suffering from a side effect not mentioned in this leaflet, consult with the doctor.

## g 5) HOW SHOULD THE MEDICINE BE STORED?

- al Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the dentist or doctor.
  - Do not use the medicine after the expiry date (Exp. Date) that appears on the package/ bottle/carton/label. The expiry date refers to the last day of that month.

**Storage conditions:** Store at a temperature below 25°C. Be sure to close the package after each use. After first opening, the medicine can be used for 3 months.

## 6) FURTHER INFORMATION:

# In addition to the active ingredient, the medicine also contains the following inactive ingredients:

1t Polyethylene Glycol 400, Polyethylene Glycol 3350, Fritzbro Artificial Wild Cherry Flavor, Sodium Saccharin.

### What the medicine looks like and the contents of the package:

The medicine looks like a viscous yellowish-brown (ivory colored) gel with a characteristic cherry odor. The gel is packed in a plastic tube with an elongated tip and a plastic cap. Each closed tube is packed in a carton box.

- st **Package size:** A tube with 5.25 grams of gel.
- al Manufacturer: Beutlich Pharmaceuticals, Bunnell, Florida, USA (together with Dental Technologies, Lincolnwood, Illinois, USA).
- **License holder:** A. Levy Dental Co. Ltd., Private Company 510917768, 27 Kalisher Street, Tel Aviv 65165.
- n **Importer:** Tree of Life Pharma Ltd., P.O.B. 799, Lod 7110604.

The format of this leaflet was determined by the Ministry of Health, and its content was checked and approved by it in 09/2014.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 142.11.32950.00