

הודעה על החמרה (מידע בטיחות) בעלון לרופא
 (מעודכן 3102.50)

תאריך 16.9.2014

שם תכשיר באנגלית HURRICAINE

מספר רישום 142.11.32950.00

שם בעל הרישום א. לוי דנטל דפו בע"מ

טופס זה מיועד לפרוט החמרות בלבד !

החמרות המבוקשות		
טקסט חדש	טקסט נוכחי	פרק בעלון
		Indication
<p>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.</p> <p>Not for use in children below the age of 12 years.</p> <p>Avoid contact with eyes.</p>		Contraindications
<p>Adults and children 2 years of age and older. Adults and children aged 12 years and over.</p> <p>Directions:</p> <ul style="list-style-type: none"> 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 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. <p>Not for use in children below the age of 12 years.</p>	<p>Do not exceed recommended dosage. Adults and children 2 years of age and older: apply a thin film to the affected area. Allow to remain in place at least 1 minute and then spit out. Use up to 4 times daily or as directed by a dentist or doctor.</p> <p>Children under 12 years of age should be supervised in the use of the product. Children under 2 years of age: risk-benefit must be considered.</p> <p>Preliminary steps prior use: Spit out, swallow or vacuum excess saliva from mouth. Remove lid from bottle and dip with a Q-Tip or cotton applicator in anesthetic gel. Collect the desired amount of anesthetic gel and place on required place of oral mucosa. Deliver a controlled amount of HURRICAINE gel to the desired area/s. Do not re-use or re-dip in the gel the Q-Tip or cotton applicator once placed mouth. This will prevent cross-contamination of the gel.</p>	Posology, dosage & administration

<p>Do not use if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics.</p>	<p>Do not use if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics.</p>	<p>Special Warnings and Special Precautions for Use</p>
		<p>Interaction with Other Medicaments and Other Forms of Interaction</p>
<p>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.</p>	<p>There is no evidence, at present, of hazard from benzocaine in pregnancy and lactation. However, only very limited data is available. Therefore it should not be used in pregnancy or lactation unless considered essential by a physician.</p>	<p>Fertility, Pregnancy and Lactation</p>
<p>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.</p>	<p>Hypersensitivity reactions to benzocaine have been reported. The incidence of allergic reaction is rare. Disorder of taste ; Methemoglobinemia – more common in infants and young children (rare).</p>	<p>Adverse events</p>
<p>There have been no reports of overdose with HURRICAINÉ Gel. Systemic effects are unlikely. Refer to current literature. 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.</p>	<p>There have been no reports of overdose with HURRICAINÉ Gel. Systemic effects are unlikely. Refer to current literature.</p>	<p>Overdosage</p>