



22.08.2022

רופא/ה נכבד/ה,

רוקח/ת נכבד/ה,

חברת רז רוקחות מבקשת להודיעכם על עדכון העלון לרופא של התכשיר:
TANTUM VERDE

בהודעה זו מצוינים רק הסעיפים בהם נעשו שינויים מהותיים בעלון לרופא.
ההחמרות סומנו בצבע **צהוב** התוספות סומנו בצבע **כחול** והמחיקות סומנו בצבע **אדום** עם קו מחיקה.
העלון המעודכן נשלח למשרד הבריאות לצורך פרסומו במאגר התרופות שבאתר משרד הבריאות:
www.health.gov.il וניתן לקבלו מודפס על ידי פנייה לבעל הרישום: רז רוקחות בע"מ, רחוב המתכת 6, א.ת. קדימה.

בברכה,

יבגני קבלרצ'יק

רוקח ממונה

מרכיב פעיל וחוזק:

BENZYDAMINE HYDROCHLORIDE 0.15 %W/V

התוויה מאושרת:

Tantum Verde is a locally acting analgesic and anti-inflammatory treatment for the relief of painful inflammatory conditions of the mouth and throat including:

Traumatic conditions: Pharyngitis following tonsillectomy or the use of a naso-gastric tube.

Inflammatory conditions: Pharyngitis, aphthous ulcers and oral ulceration due to radiation therapy.

Dentistry: For use after dental operations.

להלן העדכונים המהותיים שבוצעו בעלון לרופא:

[...]

2. Qualitative and quantitative composition

[...]

Excipient(s) with known effects:

Methyl parahydroxybenzoate

Ethanol

Mint flavour with benzyl alcohol, cinnamyl alcohol, citral, citronellol, eugenol, geraniol, isoeugenol, D- limonene and linalool.



[...]

4.2 Posology and method of administration

For oromucosal administration.

CHILDREN: Not suitable for children aged 12 years or under.

Adults and children above the age of 12: Rinse or gargle with 15 ml of Tantum Verde mouthwash for 2-3 times daily, to be used pure or diluted (in this case adding in the dosage measure 15 ml of water). Do not exceed the prescribed dose.

Method of Administration:

The solution should be expelled from the mouth after use.

Uninterrupted treatment should not exceed seven days, except under medical supervision

[...]

4.4 Special warnings and precautions for use

Benzydamine use is not advisable in patients with hypersensitivity to acetylsalicylic acid or other NSAID's.

Tantum Verde should generally be used undiluted, but if 'stinging' occurs, the rinse may be diluted with water.

Avoid contact with eyes.

This medicine contains 1.2 g of alcohol (ethanol) in each 15 ml dose.

The amount of alcohol in 15 ml of this medicine is equivalent to 30.3 ml beer or 12.12 ml wine.

The small amount of alcohol in this medicine will not have any noticeable effects.

~~This medicinal product contains 10 vol % ethanol.~~

This medicine contains Methyl hydroxybenzoate that may cause allergic reactions (possibly delayed).

This medicine contains 2mg benzyl alcohol in each 15 ml dose which is equivalent to 0.14 mg/ml. Benzyl alcohol may cause allergic reactions and mild local irritation.

This medicinal product contains mint flavour with benzyl alcohol, cinnamyl alcohol, citral, citronellol, eugenol, geraniol, isoeugenol, D - limonene and linalool. These substances may cause allergic reactions.

This medicine contains less than 1 mmol sodium (23 mg) per 15 ml dose, that is to say essentially 'sodium-free'.

[...]

6.4 Special precautions for storage

Do not store above 25 °C.

Store in the original package to protect from light.

[...]