

## **Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986**

This medicine is dispensed without a doctor's prescription

## **TANTUM VERDE Mouthwash**

### **Composition:**

#### **Active ingredient:**

Each 1ml contains 0.0015g of benzydamine hydrochloride.

For the list of inactive ingredients and allergens see section 2 – "important information about some of the ingredients of this medicine" and in section 6 - "Additional information".

### **Read the entire leaflet carefully before you start using this medicine.**

This leaflet contains concise information about this medicine. If you have any further questions, ask the doctor or the pharmacist.

### **The medicine is intended for adults and adolescents above the age of 12.**

Use the medicine according to the instructions in the section about dose in this leaflet – section 3 - "How should you use the medicine?" Consult a pharmacist if you need additional information. Refer to the doctor if the signs of the illness (symptoms) worsen or do not improve within 3 days.

### **1. What is this medicine used for?**

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

- **Inflammatory conditions** - pharyngitis, aphthous ulcers and oral ulceration due to radiation therapy.
- **Traumatic conditions** - pharyngitis following tonsillectomy or the use of a naso-gastric tube.
- **Dentistry** - for use after dental operations.

#### **Therapeutic group:**

Tantum Verde contains benzydamine hydrochloride, which belongs to the group of medicines called non-steroidal anti- inflammatory drugs (NSAIDs).

### **2. Before using this medicine**

#### **Do not use this medicine if:**

- You are sensitive (allergic) to the active ingredient benzydamine hydrochloride or to any of the other ingredients that this medicine contains (see section 6 - "Additional information and in section 2 important information about some of the ingredients of this medicine.").
- You are in the last three months of pregnancy as it could harm your unborn baby or cause problems at delivery.

#### **Special warnings regarding the use of this medicine**

##### **Before using Tentum Verde tell your doctor if:**

- You have a history of asthma.
- You are allergic to acetylsalicylic acid or to other non-steroidal anti-inflammatory drugs (NSAIDs).

#### **Children and adolescents:**

This medicine is not intended for children aged 12 years or younger.

#### **Drug interactions:**

**If you are taking or have recently taken other medicines, including non-prescription medicines and food supplements, inform your doctor or pharmacist.**

#### **Pregnancy, breastfeeding and fertility**

Consult a doctor before using this medicine if you are pregnant or breastfeeding, think you may be pregnant or are planning to be pregnant. Do not use Tantum Verde if you are in the last three months of pregnancy as it could harm your unborn baby or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected. You should not use Tantum Verde during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If you use for more than a few days from 20 weeks of pregnancy onward, Tantum Verde can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

#### **Important information about some of the ingredients of this medicine**

This medicine contains less than 1 mmol sodium (23 mg) per 15 ml dose, that is to say essentially 'sodium-free'. This medicine contains Methyl-para-hydroxy benzoate that may cause allergic reactions (possibly delayed).

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 medicine contains 2 mg 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, Linalool. These substances may cause allergic reactions.

### **3. How should you use the medicine?**

Check with the doctor or the pharmacist if you are not sure about the dosage and treatment regimen of the medicine. The usual recommended dose:

- Adults and children above the age of 12:** 15 ml of Tantum Verde 2-3 times a day,
- Do not use this medicine for more than 7 days in a row, unless you have been instructed otherwise by your doctor or dentist.
  - The mouthwash can be used undiluted, but if you experience "stinging", you may dilute it with water to reduce this sensation.
  - Tantum Verde is intended for use as a gargle in the throat or as a mouthwash. Rinse the mouth or gargle according to the following instructions:

**Use without dilution:** Pour 15 ml of Tantum Verde into the measuring cup,

gargle in the mouth for 20- 30 seconds and spit out.

**Use following dilution:** Pour 15 ml of Tantum Verde into the measuring cup and add 15 ml of water into the measuring cup up to the line indicating 30 ml. Gargle in the mouth for 20-30 seconds and spit out.

- Following use, wash the measuring cup and store it in a safe place for further use.

**- Do not swallow! Use only in the oral cavity.**

**- If your condition worsens or does not improve, contact a doctor.**

**Do not exceed the recommended dose.**

**If you have accidentally taken an overdose, swallowed the medicine or if a child has accidentally swallowed the medicine,** immediately contact a doctor or go to a hospital emergency room and take the medicine package with you.

**If you forget to use this medicine at the scheduled time, do not take a double dose. Take the next dose at the usual time and consult your doctor.**

**Do not use Tantum Verde in or near your eyes. If any oral rinse gets in your eyes, wash them immediately with cold water.**

**Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.**

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

### **4. Side effects**

As with any medicine, the use of Tantum Verde can cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

**Some of the side effects can be severe. If you experience any of the following symptoms, seek medical assistance immediately:**

Severe allergic reactions (anaphylactic shock), which can include difficulties breathing, chest pain or chest tightness, and/or feeling faint/dizzy, severe skin itching or raised lumps on the skin, swelling of the face, lips, tongue and/or throat. All these side effects can be life threatening. Seek immediate medical help.

**Additional side effects, if any of them become serious contact your doctor:**

**Uncommon side effects (effects that occur in 1-10 users out of 1,000):**

Numbness and/or stinging in the mouth and/or throat.

**Very rare side effects (effects that occur in less than 1 user out of 10,000):**

- Difficulty breathing and wheezing.
- Itching.
- Skin rash.

**Side effects with unknown frequency (effects whose frequency has not yet been determined):**

- Skin redness or swelling.
- Allergic reaction (Hypersensitivity).

**If a side effect occurs, if any of the side effects worsens, or if you suffer from a side effect which is not mentioned in this leaflet, consult your doctor.**

#### **Reporting side effects:**

Side effects can be reported to the Ministry of Health by clicking the link

"report side effects due to medication" that can be found on the homepage of the Ministry of Health website ([www.health.gov.il](http://www.health.gov.il)) directing to an online form for reporting side effects, or by clicking the link: <https://sideeffects.health.gov.il>.

### **5. How to store the medicine?**

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the outer package. The expiry date refers to the last day of that month.

#### **Storage Conditions:**

- Store below 25°C.
- Store in the original package to protect from light.
- Following the first opening, the solution can be used until the expiration date of the medicine.
- The medicinal products must not be thrown in the wastewater or in household waste. Ask your pharmacist how to dispose of medicinal products that are no longer required. This will help to protect the environment.

### **6. Additional information**

#### **In addition to the active ingredient the medicine also contains:**

Ethanol 96%, Glycerol, Methyl parahydroxybenzoate, Mint flavour, Saccharin, Sodium hydrogen carbonate, Polysorbate 20, Quinoline yellow 70% (E104), Patent blue V 85% (E131), Purified water.

#### **What does the medicine look like and what are the contents of the package:**

Tantum Verde mouthwash is a clear, green solution marketed in 120ml or 240ml bottles with a measuring cup. Not all pack sizes may be marketed

#### **Marketing Authorization Holder and Importer:**

RAZ Pharmaceuticals Ltd., 31 Gesher haetz Street, Emek Hefer Industrial Park, Israel

#### **Drug registration number at the national drug registry of the Ministry of Health:**

140-35-31801-00.

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