

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

This medicine is to be supplied without doctor's prescription

TANTUM VERDE

Mouthwash

Composition:

Each 100 ml of solution contains:

Benzydamine Hydrochloride 0.15 g.

For the list of inactive ingredients – see section 6, "Additional information".

Read the entire leaflet carefully before you start using this medicine. This leaflet contains essential information about this medicine. If you have any further questions, refer to the doctor or to the pharmacist.

The medicine is intended for adults and adolescents above the age of 12. take the medicine according to the instructions in the section about dose in this leaflet. Consult a pharmacist if you need additional information. Refer to the doctor if the signs of the illness (symptoms) get worse or do not improve after 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").

Warnings

Talk to your doctor, pharmacist or nurse before using this medicine:

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

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 breast-feeding, think you may be pregnant or are planning to be pregnant.

Important information about some of the medicine's ingredients

This medicine contains glycerol that can cause headaches, stomach discomfort and diarrhea.

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 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.

3. How should you use the medicine?

Use the medicine always according to your doctor's instructions. Check with the doctor or the pharmacist if you are not sure.

- The usual recommended dose for 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 mouthwash 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 take the 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 mouthwash in or near your eyes. If any oral rinse gets in your eyes, wash them immediately with cold water.

How can you contribute to the success of the treatment?

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 mouthwash 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 appear in 1-10 users out of 1,000):

Numbness and/or stinging in the mouth and/or throat (if this solution causes you stinging in the mouth, you can dilute the next dose with water as stated in section 3).

Very rare side effects - effects that appear 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 any of the side effects worsen, or if you experience side effects not mentioned in this leaflet, consult your doctor.

Reporting side effects:

You can report side effects to the Ministry of Health by clicking the "report side effects due to medication" in the homepage of the Ministry of Health (www.health.gov.il) referring 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 should be kept in a closed place out of the reach and sight of children and/or infants in order 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.
- 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 waste water and in household waste. Ask your pharmacist how to dispose the 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 green solution marketed in 120ml or 240ml bottles with a measuring cup.

Manufacturer and his address:

Azienda Chimiche Riunite Angelini Francesco (A.C.R.A.F.) SPA, Ancona, Italy.

Marketing Authorization Holder and his address:

RAZ Pharmaceuticals Ltd., 6 Hamatechet St., Kadima, Israel.

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

140-35-31801-00.

This leaflet was revised in May 2022 according to MOHs guidelines.

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