

PACKAGE LEAFLET: INFORMATION FOR THE USER

TANTUM VERDE

1.5 mg / ml, oromucosal spray

BENZYDAMINE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What TANTUM VERDE is and what it is used for
2. Before you take TANTUM VERDE
3. How to take use TANTUM VERDE
4. Possible side effects
5. How to store TANTUM VERDE
6. Further information

1. WHAT TANTUM VERDE IS AND WHAT IT IS USED FOR

TANTUM VERDE spray possesses significant anti-inflammatory, disinfectant and pain relieving effects. Spray is effective in treatment of inflammatory processes accompanied with pain in mouth cavity or throat.

TANTUM VERDE is used for the symptomatic treatment of irritation / inflammation of the throat and oral cavity, including pain in the oropharyngeal region (gingivitis, stomatitis or pharyngitis), after a tooth extraction or conservative dental treatment.

2. BEFORE YOU TAKE TANTUM VERDE

Do not take TANTUM VERDE

If you are allergic (hypersensitive) to benzydamine hydrochloride or any of the other ingredients of the product,

Take special care with TANTUM VERDE

No special precautions are necessary during the administration of Tantum Verde, oromucosal spray.

Contact your doctor if there are no significant signs of improvement after several days of administration of the medicine.

Use of benzydamine, especially long-term use can cause sensitization phenomenon. In this case, discontinue the treatment and consult a doctor who will prescribe the appropriate treatment.

The product is particularly suitable for those patients who have difficulties with gargling.

In a limited number of patients ulceration of the oropharynx may be a sign of serious illness and therefore if symptoms last longer than 3 days the patient must contact a doctor or dentist (as needed).

Use of benzydamine is not recommended in patients allergic to salicylic acid or other non-steroidal anti-inflammatory drugs.

Medicine should be administered with caution in patients who have a history of bronchial asthma attacks, because in these patients it may cause a spasm of the bronchi.

Tantum Verde contains parahydroxybenzoate which may cause allergic reactions (including delayed allergic reactions).

Information for athletes: the use of medicines containing ethyl alcohol could lead to positive results in anti-doping tests that are based on the presence of alcohol in the blood.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription and herbal medicines. No interactions with other concomitantly used medicines are known.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine. Even though the performed studies have not revealed any harmful effects on fetus, the product should be used during pregnancy only after consultation with a doctor. Breast-feeding women must not use the product.

Talk to your pharmacist or doctor before taking TANTUM VERDE Oromucosal if you are pregnant, planning to become pregnant or are breast feeding.

Driving and using machines

It is not likely that TANTUM VERDE will affect your ability to drive and use machines.

Other warnings

Tantum Verde contains parahydroxybenzoate which can cause an allergic reaction (sometimes even late).

3. HOW TO TAKE TANTUM VERDE

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Dosage

Adults and children over 12 years: 4 - 8 sprays 2 - 6 times a day.

Pediatric use: children over 6 and below 12: 4 sprays 2 - 6 times a day.

Children (under 6 years): 1 spray per 4 kg of body weight, a maximum of 4 sprays at once, 2-6 times a day.

Warning: The recommended dose should not be exceeded without prior consultation with a doctor.

If symptoms persist, consult your doctor.

The product should be applied with intervals 1.5 - 3 hours between applications.

Instructions for use:

1. Turn the cannula (white tube) to be vertical to the bottle.
2. Insert the cannula at your mouth and aim at the inflamed place in your mouth or throat.
3. Press strongly the dosing pump on the top of the bottle as many times as prescribed doses. One press means one dose. Hold your breath during application.

Before the first use, spray several times into the air to assure equal doses application. You must talk to a doctor if you do not feel better or if you feel worse after 7 days, or if a fewer or other signs appear. Do not use the product longer than 14 days without consulting your doctor

If you take more TANTUM VERDE than you should

If you take more of this medicine than you should, talk to a doctor or go to a hospital straight away. If someone accidentally swallows this spray, they need to contact a doctor or the nearest hospital with an emergency department. Take the medicine pack with you.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

Like all medicines, TANTUM VERDE can cause side effects, although not everybody gets them.

Side effects are classified according to frequency: very common: $\geq 1 / 10$; common: (1/10 - 1/100), uncommon (1/100 - 1/1000); rare (1 / 1,000 to 1 / 10,000); very rare (<1 / 10,000), Not known: frequency cannot be determined from the available data.

Uncommon: photosensitivity (increased sensitivity to sunlight)

Rare: burning sensation, dry mouth and hypersensitivity reactions

Very rare: laryngospasm (spasm of the larynx), angioedema (swelling of mucous membranes and skin).

Not known: anaphylactic reactions (hypersensitivity reactions, eg. Hives).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE TANTUM VERDE

Keep out of the reach and sight of children.

Do not store above 30 °C.

Do not use TANTUM VERDE after the expiry date which is stated on the label, 4 years from the date of manufacture.

6. FURTHER INFORMATION

What TANTUM VERDE contains

1 ml of spray contains 1.5 mg of benzydamine hydrochloride.

100 mL of spray Tantum Verde oromucosal contains 0.15 g of benzydamine hydrochloride (equivalent to 0.134 g benzydamine).

Other ingredients: glycerol, sorbitol liquid, crystalline, sodium saccharin, acesulfame K, methyl parahydroxybenzoate, propyl parahydroxybenzoate, menthol flavor, polysorbate 20, purified water.

What TANTUM VERDE looks like and contents of the pack

A cardboard box with a bottle with a sprayer, 30 ml of oromucosal spray.

Regime of dispensing

The medicine is issued without doctor`s prescription.

Manufacturer

Aziende Chimiche Riunite Angelini Francesco- A.C.R.A.F. S.p.A.
Via Amelia 70, 00181 Rome,
Italy

Manufacturer of the medicinal product

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