TANTUM VERDE®

INFORMATION LEAFLET
for the medicinal product

Composition:
active substance: **benzydamine hydrochloride**;
100 mL of solution contain benzydamine hydrochloride 0.15 g;
excipients: ethanol 96%, glycerol, methyl parahydroxybenzoate (E 218), flavor (menthol), saccharin, sodium hydrocarbonate, Polysorbate 20, Quinoline Yellow (E 104), Patent Blue V (E 131), purified water.

Dosage form. Oromucosal solution.
Basic physical and chemical properties: a clear green liquid with a typical mint flavor.

Pharmacotherapeutic group. Dental preparations. Other agents for local oral treatment.
ATC code: A01A D02.

Pharmacological properties.
Pharmacodynamics.
Benzydamine is a non-steroidal anti-inflammatory drug (NSAID) with analgesic and antiexudative properties.

Clinical studies have shown that benzydamine is effective in the relief of symptoms accompanying localized irritation conditions of the oral cavity and pharynx. Moreover, benzydamine has anti-inflammatory and local analgesic properties, and also exerts a local anesthetic effect on the oral mucosa.

Pharmacokinetics.
Absorption through the oral and pharyngeal mucosa has been proven by the presence of measurable quantities of benzydamine in human plasma. However, they are insufficient to produce any systemic pharmacological effect. The excretion occurs mainly in urine, mostly as inactive metabolites or conjugated compounds.

When applied locally, benzydamine has been shown to cumulate in inflamed tissues in an effective concentration due to its ability to permeate through the mucous membrane.

Clinical particulars.
Indications.
Symptomatic treatment of oropharyngeal irritation and inflammation; to relieve pain caused by gingivitis, stomatitis, pharyngitis; in dentistry after tooth extraction or as a preventive measure.
Contraindications.
Hypersensitivity to the active substance or to any other ingredients of the product.

Interaction with other medicinal products and other types of interaction.
No drug interaction studies have been performed.

Warnings and precautions.
If sensitivity develops with long-term use, the treatment should be discontinued and a doctor should be consulted to get appropriate treatment.

In some patients, buccal/pharyngeal ulceration may be caused by severe pathological processes. Therefore, the patients, whose symptoms worsen or do not improve within 3 days or who appear feverish or develop other symptoms, should seek advice of a physician or a dentist, as appropriate.

Benzydamine is not recommended for use in patients hypersensitive to acetylsalicylic acid or other non-steroidal anti-inflammatory drugs (NSAIDs).

The product can trigger bronchospasm in patients suffering from or with a history of asthma. Such patients should be warned of this.

For athletes: the use of medicinal products containing ethyl alcohol might result in positive antidoping tests considering the limits established by some sports federations.

Use during pregnancy or breast-feeding
No adequate data are currently available on the use of benzydamine in pregnant and breastfeeding women. Excretion of the product into breast milk has not been studied. The findings of animal studies are insufficient to make any conclusions about the effects of this product during pregnancy and lactation.

The potential risk for humans is unknown.

TANTUM VERDE should not be used during pregnancy or breast-feeding.

Effects on reaction time when driving or using machines
When used in recommended doses, the product does not produce any effect on the ability to drive and operate machinery.

Method of administration and doses.
Pour 15 mL of TANTUM VERDE solution from the bottle into the measuring cup and gargle with undiluted or diluted product (15 mL of the measured solution can be diluted with 15 mL of water). Gargle 2 or 3 times daily. Do not exceed the recommended dose.

Children.
The product should not be used in children under 12 years due to a possibility of ingestion of the solution when gargling.

Overdosage.
No overdose has been reported with benzydamine when used locally. However, it is known that benzydamine, when ingested in high doses (hundreds times higher than those possible with this dosage form), especially in children, can cause agitation, convulsions, tremor, nausea, increased sweating, ataxia, and vomiting. Such acute overdose requires immediate gastric lavage, treatment of fluid/salt imbalance, symptomatic treatment, and adequate hydration.

Adverse reactions.
Within each frequency group, the undesirable effects are presented in order of their decreasing seriousness.

Adverse reactions are classified according to their frequency: very common (≥ 1/10); common (≥ 1/100 to <1/10); uncommon (≥ 1/1,000 to <1/100); rare (≥ 1/10,000 to <1/1,000); very rare (<1/10,000); frequency unknown (cannot be estimated from the available data).

Gastrointestinal disorders: rare – burning mouth, dry mouth; *unknown* – oral hypesthesia, nausea, vomiting, tongue edema and discoloration, dysgeusia.

Immune system disorders: rare – hypersensitivity reaction, *unknown* - anaphylactic reaction.

Respiratory, thoracic and mediastinal disorders: very rare –laryngospasm; *unknown* – bronchospasm.

Skin and subcutaneous tissue disorders: uncommon – photosensitivity; *very rare* – angioedema; *unknown* – rash, pruritus, urticaria.

Nervous system disorders: unknown – dizziness, headache.

TANTUM VERDE contains methyl parahydroxybenzoate, which can cause allergic reactions (including delayed-type reactions).

Shelf life. 4 years.

Storage conditions.
Do not store above 25°C. Keep out of reach of children.

Packaging.
120 mL of solution in a bottle with a measuring cup; 1 bottle per cardboard box.

Dispensing category.
Over-the-counter medicinal product.

Manufacturer.
Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A., Italy.

Location of the manufacturer and its business address. Via Vecchia del Pinocchio, 22 – 60100 Ancona (AN), Italy.

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Information leaflet is

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