Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Tantum verde orange-honey taste 3 mg lozenges

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each lozenge contains 3 mg of benzydamine hydrochloride equivalent to 2.68 mg of benzydamine.

Excipients with known effects: each lozenge contains 3073.53 mg of Isomalt (E 953) and 0.017 mg of Sunset yellow (E 110).

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Lozenge.
Orange-yellow square-shaped lozenges, with a central cavity.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Tantum Verde is indicated in adults and children over 6 years of age, for symptomatic local treatment for the relief of pain and irritation of mouth and throat.

4.2 Posology and method of administration

Posology
Adults and children over 6 years of age: one lozenge 3 times a day.
The treatment must not exceed 7 days.

Pediatric population
Children 6-11 years of age:
The medicinal product should be administered under adult supervision.
Children below 6 years of age:
Due to the type of the pharmaceutical form, the administration should be restricted to children of more than 6 years of age.

Method of administration
For oropharingeal use.
Lozenge should be dissolved slowly in the mouth
Do not swallow. Do not chew.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Benzydamine use is not advisable in patient with hypersensitivity to salicylic acid or other NSAIDs.
Bronchospasm may be precipitated in patients suffering from or with a previous history of bronchial asthma. Caution should be exercised in these patients.

In a minority of patients, buccal/pharyngeal ulceration may be caused by serious disease processes. Patients whose symptoms worsen or do not improve within 3 days, or who appear feverish or have other symptoms, must therefore seek the advice of their doctor or dentist as appropriate.
Tantum Verde P contains:

- **Isomalt**: patients with rare hereditary problems of fructose intolerance should not take this medicine.
- **Sunset yellow (E 110):** may cause allergic reactions.

4.5 Interaction with other medicinal products and other forms of interactions

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no or limited amount of data from the use of benzydamine in pregnant women, and animal studies are insufficient with respect to reproductive toxicity (see section 5.3).
Tantum Verde should not be used during pregnancy.

Breast-feeding
There is insufficient information on the excretion of benzydamine in human milk.
Tantum Verde should not be used during breast-feeding.

4.7 Effects on ability to drive and use machines

Tantum Verde has no or negligible influence on the ability to drive and use machine, when it is used at the recommended dose.

4.8 Undesirable effects

Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness

The following rate values have been used: 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) and Very rare (<1/10,000), not known (cannot be estimated from the available data).

System-Organ Class	Frequency	Undesirable effect
Immune system disorders	*Not Known*	Anaphylactic reaction, Hypersensitivity reaction
Respiratory, thoracic, and mediastinal disorders	*Very rare*	Laryngospasm
Gastrointestinal Disorders	*Rare*	Burning mouth, Dry mouth
	Not known	Hypoaesthesia oral
Skin and subcutaneous tissue disorders	*Uncommon*	Photosensitivity
	Very rare	Angioedema

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Symptoms
No overdosage with the lozenge formulation has been reported. However, very rarely in children excitation, convulsions, sweating, ataxia, tremor and vomiting have been reported after the oral administration of benzydamine dosages about 100 times higher than those of the lozenge.

Management
In the event of acute overdosage only symptomatic treatment is possible; the stomach should be emptied by inducing vomiting or by gastric lavage, and the patient carefully observed and given supportive treatment. Adequate hydration must be maintained.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: other throat preparations, ATC code: R02AX03

Clinical efficacy and safety
Clinical studies demonstrate that benzydamine is effective in relieving suffering from localised irritation processes of the mouth and pharynx. In addition, benzydamine possesses a moderate local anaesthetic effect.

5.2 Pharmacokinetic properties

Absorption
The absorption through the mucosa of the mouth and pharynx was demonstrated by the presence of measurable quantities of benzydamine in the human plasma.

Distribution
About 2 hours after the 3 mg lozenge administration, benzydamine peak plasma values of 37.8 ng/ml with an AUC of 367 ng/ml*h were observed. However, these levels are not sufficient to produce pharmacological systemic effects.
When locally applied benzydamine has been shown to accumulate in inflamed tissues where it reaches effective concentrations because of its capacity to penetrate the epithelial lining.

Biotransformation and elimination
The excretion occurs mainly in the urine and mostly in the form of inactive metabolites or conjugation products.

5.3 Preclinical safety data

Development and peri-post natal toxicity was seen in reproductive toxicity studies in rats and rabbits at plasma concentration much higher (up to 40 times) than those observed after a single therapeutic oral dose. No teratogenic effects were seen in those studies. Available kinetic data do not allow to establish the clinical relevance of the reproductive toxicity studies. As the preclinical studies had shortcomings and therefore are of restricted value, they do not provide additional information relevant for the prescriber beyond that included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Isomalt (E 953)
Citric acid, monohydrate
Orange flavour
Honey flavour
Levomenthol
Acesulfame potassium
Quinoline yellow (E 104)
Sunset yellow (E 110)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

4 years

6.4 Special precautions for storage

Do not store above 30°C.
Store in original package in order to protect from moisture.

6.5 Nature and contents of container

Lozenge wrapped in paraffin paper.
Ten lozenges are wrapped together in printed polyethylene-paper-aluminium trilaminated material.
Each pack contains 20 or 30 lozenges (two or three packets of ten lozenges each).
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.
Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Aziende Chimiche Riunite Angelini Francesco
Viale Amelia 70, 00181
Rome
Italy

8 MARKETING AUTHORISATION NUMBER

PA0959/001/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 5th November 2010
Date of last renewal: 30th May 2013

10 DATE OF REVISION OF THE TEXT

October 2020