PACKAGE LEAFLET: INFORMATION FOR THE USER

Tantum Verde lemon taste 3 mg lozenges,
Benzydamine Hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Always take this medicine exactly as described in this leaflet or as your doctor, or pharmacist have told you. Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

What is in this leaflet:
1. What Tantum Verde is and what it is used for
2. What you need to know before you take Tantum Verde
3. How to take Tantum Verde
4. Possible side effects
5. How to store Tantum Verde
6. Contents of the pack and other information

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

Tantum Verde contains the active substance benzydamine, which belongs to the group of agent for oral local treatment ,.
Tantum Verde is used in adults and children above 6 years of age, for symptomatic local treatment for the relief of pain and irritation of the mouth and throat.

You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TANTUM VERDE

Do not take Tantum Verde P:

- If you are allergic to benzydamine or any of the other ingredients of this medicine (listed in section 6).

Warnings and precaution:
Talk to your doctor or pharmacist before taking Tantum Verde:

- If you suffer from a condition known as phenylketonuria.
- If you have a history of Asthma.
- If you are allergic to acetylsalicylic acid or to other anti-inflammatory painkillers called NSAIDs.
- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
- If after using the lozenges the pain in your mouth or throat gets worse or does not improve within 3 days, or you appear feverish or have other symptoms, you should speak to your doctor or dentist.

Other medicines and Tantum Verde

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

Tantum Verde with food and drink

Food and drink have no influence.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding,, think you may be pregnant or are planning to have a baby , ask your doctor or pharmacist for advice before taking this medicine.
Tantum Verde P is not recommended during pregnancy.
Tantum Verde P should not be used during breast-feeding.

Driving and using machines

Tantum Verde does not affect your ability to drive or use machines.

Tantum Verde contains

This medicinal product contains Isomalt. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
The medicinal product contains also Aspartame a source of phenylalanine. May be harmful for people with phenylketonuria.

3. HOW TO TAKE TANTUM VERDE

Always take 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.

The recommended dose is:
Adults and children over 6 years old: one lozenge 3 times a day. Do not take more than 3 lozenges per day.

Use in children
Children from 6 to 11 years old: this medicinal product should be administered under an adult supervision.
The pharmaceutical form “lozenges” should not be given to children under the age of 6 years.

Tantum Verde should not be used for more than 7 days. Oropharyngeal use.
Let one lozenge dissolve slowly in the mouth.
Do not swallow.
Do not chew.

If you take more Tantum Verde than you should

If you accidentally take too many lozenges, you should contact your pharmacist, doctor or nearest hospital casualty department immediately. Always take the labelled medicine package with you, whether there are any lozenges left or not.
Although very rarely, the symptoms of overdose reported in children are excitation, convulsions, sweating, ataxia, tremor and vomiting after the oral administration of benzydamine dosages about 100 times higher than those of the lozenge.

If you have any further questions on the use of this product ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side-effects, although not everybody gets them.

Uncommon (may affect up to 1in 100 people):
- Skin sensitivity to sunlight (causing a rash or sunburn).

Rare (may affect up to 1 in 1,000 people):
- Burning sensation or dryness of the mouth. If this happens to you, try sipping a glass of water to reduce the effect.
- Allergic reaction, rash or itching especially if affecting the whole body (hypersensitivity reaction).

Very rare (may affect up to 1 in 10,000 people):
- sudden swelling in the mouth/throat and mucous membranes (angioedema).
- difficulty breathing (laryngospasm).

Not known (frequency cannot be estimated from the available data):
- severe allergic reactions (anaphylactic reactions)
- Local loss of sensitivity of the oral mucosa (Hypoaesthesia oral)

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly 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. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE TANTUM VERDE

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.
Store in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Tantum Verde contains:

- The active substance is benzydamine.
- Each lozenge contains 3 mg of benzydamine hydrochloride equivalent to 2.68 mg benzydamine. The other excipients are: Isomalt (E 953), Aspartame (E951), Citric acid monohydrate, Lemon flavour, Mint flavour, Quinoline yellow (E104), Indigotin dye (E132).

What Tantum Verde looks like and contents of the pack
This medicinal product is presented as yellow-green, square shaped lozenges with a central cavity, wrapped in paper. Pack sizes of 20 lozenges and 30 lozenges.
Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer
The Marketing Authorisation Holder is:
A.C.R.A.F. S.p.A., Viale Amelia, 70,
00181 Rome, Italy

The Manufacturers are:
A.C.R.A.F. S.p.A.,
Via Vecchia del Pinocchio,22
60131 – Ancona, Italy

PIERRE FABRE MEDICAMENT PRODUCTION
Site Diététique et Pharmacie
Zone Industrielle de la Coudette
32290 Aignan, France

This medicinal product is authorised in the Member States of the EEA under the following names:

Italy: ***Tantum Verde P, 3mg pastiglie gusto limone***
Portugal: ***Tantum Verde®, pastilhas, 3 mg, sabor a limão***
Spain: ***Tantum Verde 3 mg pastillas para chupar sabor limon***
Germany: ***Tantum Verde mit Zitronengeschmack 3 mg Lutschtabletten***
Denmark: ***Zyx mit Zitronengeschmack 3mg sugetabletter***
*Sweden****: Zyx Citron 3 mg sugtabletter***
Ireland: ***Tantum Verde lemon taste 3mg lozenges***
UK: ***Difflam 3 mg Lozenges, lemon taste***
France: ***Benzydamine A.C.R.A.F., 3mg arome citron, pastille***
*Luxembourg:****Tantum Verde***
*Netherlands****: Tantum Verde P citroensmaak, zuigtabletten 3 mg***

This leaflet was last revised in
To be completed nationally