

PACKAGE LEAFLET: INFORMATION FOR THE USER

BRONCHOSTOP *Cough Syrup*

Active substances: thyme liquid extract, marshmallow root liquid extract

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 has 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 your doctor if you do not feel better or if you feel worse after 5 days.

What is in this leaflet:

1. What *BRONCHOSTOP Cough Syrup* is and what it is used for
2. What you need to know before you take *BRONCHOSTOP Cough Syrup*
3. How to take *BRONCHOSTOP Cough Syrup*
4. Possible side effects
5. How to store *BRONCHOSTOP Cough Syrup*
6. Contents of the pack and other information

1. What *BRONCHOSTOP Cough Syrup* is and what it is used for

Traditional herbal medicinal product to relieve irritation of the throat and to promote the expectoration of viscous mucus in cough associated with cold.

The product is a traditional herbal medicinal product for use in the specified indications exclusively based upon long-standing use.

You must talk to a doctor if you do not feel better or if you feel worse after 5 days.

2. What you need to know before you take *BRONCHOSTOP Cough Syrup*

Do not take *BRONCHOSTOP Thyme Marshmallow Cough Syrup*

if you are allergic to the active substance(s), to other members of the Lamiaceae family or to any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking *BRONCHOSTOP Cough Syrup*.

In case of fever, shortness of breath or purulent discharge, a doctor should be consulted.

Children

The use in children under 4 years of age is not recommended due to lack of data and because medical advice should be sought.

Other medicines and *BRONCHOSTOP Cough Syrup*

Please inform your doctor or pharmacist if you are taking/using or have recently taken/used any other medicines, including medicines obtained without a prescription.

No interactions with other medicinal products are known.

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.

The alcohol content is to be considered in case of pregnancy and breast-feeding.

In the absence of sufficient data the use during pregnancy and breast-feeding is not recommended.

Driving and using machines

No investigations on the effects on the ability to drive and to use machines have been performed.

Important information about some of the ingredients of *BRONCHOSTOP Cough Syrup* contains *ethanol, saccharose, glucose, fructose, methyl-4-hydroxybenzoate and propyl-4-hydroxybenzoate*

- This medicinal product contains 285 mg ethanol per 5 ml. The alcohol content of an individual dose for adults and adolescents from the age of twelve years corresponds to 14.36 ml beer and 5.98 ml wine. The alcohol content of an individual dose for children aged between four and twelve years corresponds to 7.18 ml beer and 2.99 ml wine. (see section 2 warnings and precautions).
- This medicinal product contains 1.75 g saccharose and 15.3 mg fructose per 5 ml, corresponding to approximately 0.15 carbohydrate units (CU). This should be taken into account in patients with diabetes mellitus.
- If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

- *BRONCHOSTOP Cough Syrup* contains the preservatives methyl-4-hydroxybenzoate and propyl-4-hydroxybenzoate. These may cause allergic reactions which may also appear as a delayed reaction (see "Do not take *BRONCHOSTOP Cough Syrup* ").

3. How to take *BRONCHOSTOP Cough Syrup*

Always take this medicine exactly as described in this package leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist, if you are not sure.

The recommended dose is:

Adults and adolescents over 12 years of age:

10 ml every 3 hours up to 6 times per day; maximum daily dose up to 60 ml.

Children between 4 – 12 years of age:

5 ml every 3 hours up to 6 times per day; maximum dose up to 30 ml.

Children aged less than 4 years:

The use in children under 4 years of age is not recommended due to lack of data and because medical advice should be sought.

Method of administration:

For oral use.

Take *BRONCHOSTOP Cough Syrup* undiluted, by putting the abovementioned dose into the enclosed measuring cup which has a 2.5 ml to 20 ml scale.

If required, you may take *BRONCHOSTOP Cough Syrup* diluted in water or warm tea.

Duration of treatment:

You must talk to a doctor if you do not feel better or if you feel worse after 5 days.

If you take more *BRONCHOSTOP Cough Syrup* than you should

If you have taken a considerable overdose of this medicinal product, symptoms of known undesirable effects may occur more intensively. In this case, please notify your doctor.

If necessary, he/she can make a decision on any measures required.

If you forget to take *BRONCHOSTOP Cough Syrup*

Do not take a double dose to make up for a forgotten dose.

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

4. Possible side effects

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

Hypersensitivity reactions as well as stomach disorders have been observed in connection with medicinal products containing thyme. The frequency of occurrence is not known.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the national reporting system:

Bundesamt für Sicherheit im Gesundheitswesen
Traisengasse 5
1200 VIENNA
AUSTRIA
Fax: + 43 (0) 50 555 36207
Website: <http://www.basg.gv.at/>

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store *BRONCHOSTOP Cough Syrup*

Unopened this medicine does not require any special temperature storage conditions.
After first opening do not store above 25 °C.

Store the bottle in the original package in order to protect the contents from light.

Keep the bottle tightly closed.

Keep out of the reach and sight of children.

Do not use this medicine after the expiry date which is stated on the carton after “Use by”. The expiry date refers to the last day of that month.

After opening the bottle, use the contents within 4 weeks.

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 protect the environment.

6. Contents of the pack and other information

What *BRONCHOSTOP Cough Syrup* contains

The active substances are:

5 ml (= 5.7 g) contains:

0.77 g thyme liquid extract (Thymi herba, drug-extract ratio = 1:2-2.5, extraction agent: mixture of ethanol 90% (v/v):ammonia solution 10% (m/m):glycerol 85% (m/m):water at a ratio of 35:0.5:10:54.5)

0.66 g marshmallow root liquid extract (Althaeae radix, drug-extract ratio = 1:20, extraction agent water)

The other ingredients are:

Raspberry juice concentrate (containing sucrose, glucose and fructose), ascorbic acid, ethanol, saccharose, methyl-4-hydroxybenzoate, propyl-4-hydroxybenzoate, purified water.

What *BRONCHOSTOP Cough Syrup* looks like and contents of the pack

BRONCHOSTOP Cough Syrup is a brown-red, viscous solution for oral use, with the scent and taste of thyme and raspberries. The syrup is filled into brown glass bottles with a sealed screw cap, in a 150 ml size. The enclosed measuring cup with a scale between 2.5 ml and 20 ml facilitates precise measuring of the recommended dosage.

Flocculations may occur and may also appear as sediment or as deposit on the inner side of the screw cap. These flocculations have no influence on the efficacy or quality of the medicinal product.

Marketing authorisation holder and manufacturer

Kwizda Pharma GmbH, A-1160 Vienna
www.bronchostop.at

Reg. no.:

This information for the user was last amended in October 2019.