

PACKAGE LEAFLET: INFORMATION FOR THE USER

BRONCHOSTOP sine Cough Syrup

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

1. What *BRONCHOSTOP sine 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 registered 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 sine Cough Syrup*

Do not take *BRONCHOSTOP sine Cough Syrup*

if you are allergic to thyme herb, marshmallow root, 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 sine Cough Syrup*. In case of fever, shortness of breath or purulent discharge, a doctor should be consulted.

Children

The use in children under 2 years of age is not recommended due to lack of data and because medical advice should be sought.

Other medicines and *BRONCHOSTOP sine Cough Syrup*

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines.

No interactions with other medicinal products are known.

Pregnancy and breast-feeding

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

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.

Driving and using machines

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

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

***BRONCHOSTOP sine Cough Syrup* contains raspberry juice concentrate which contains saccharose, glucose and fructose.**

This medicine contains 66 mg fructose in 15 ml *BRONCHOSTOP sine Cough Syrup*.

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 sine Cough Syrup* contains propylene glycol.**

This medicine contains 38.9 mg of propylene glycol in 15 ml dose.

This medicine contains less than 1 mmol sodium (23 mg) per 15 ml dose, that is to say essentially 'sodium-free'.

3. How to take *BRONCHOSTOP sine 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:

15 ml every 3 to 4 hours (4 to 6 times per day; maximum daily dose up to 90 ml)

Children between 4 – 11 years of age:

7.5 ml every 3 to 4 hours (4 to 6 times per day; maximum daily dose up to 45 ml)

Children between 2 – 3 years of age:

After consultation with a doctor, 7.5 ml every 3 to 4 hours (4 to 6 times per day; maximum daily dose up to 45 ml) may be administered.

Children aged less than 2 years:

The use in children under 2 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 sine 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 sine Cough Syrup* diluted in water or warm tea.

Duration of administration:

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

If you take more *BRONCHOSTOP sine 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 sine 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 sine Cough Syrup*

Do not store above 25 °C.

Store the bottle in the original package in order to protect the contents from light. Close the bottle tightly after use.

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 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 sine Cough Syrup* contains

The active substances are:

15 ml (= 16.7 g) contains:

0.12 g thyme dry extract (Thymi herba, drug-extract ratio = 7-13:1 (DER), extraction agent: water)

0.83 g marshmallow root liquid extract (Althaeae radix, drug-extract ratio = 1:13 (DER), extraction agent: water)

The other ingredients are:

Xylitol (E 967), methyl-4-hydroxybenzoate (E 218), propyl-4-hydroxybenzoate (E 216), raspberry juice concentrate (containing saccharose, glucose und fructose), raspberry flavour (containing propylene glycol (E 1520)), Xanthan gum, citric acid monohydrate (E 330), maltodextrin, gum Arabic, glycerol (E422), saccharin sodium (E954), neohesperidin-dihydrochalcone, purified water.

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

BRONCHOSTOP sine Cough Syrup is a brown-red, viscous solution with the scent and taste of thyme and raspberries. It is filled into brown glass bottles with a sealed screw cap, in 100 ml, 120 ml, 150 ml and 200 ml sizes. Not all pack sizes will necessarily be marketed.

The enclosed measuring cup with a scale between 2.5 ml and 20 ml facilitates precise measuring of the recommended amount.

Marketing Authorisation Holder and Manufacturer

Kwizda Pharma GmbH, Effingergasse 21, 1160 Wien

www.bronchostop.at

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