

Package Leaflet: Information for patients

BRONCHOSTOP Cough Pastilles

Active substance: thyme herb dry 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 of the 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 Pastilles* are and what they are used for?
2. What you need to know before you take *BRONCHOSTOP Cough Pastilles*?
3. How to take *BRONCHOSTOP Cough Pastilles*?
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5. How to store *BRONCHOSTOP Cough Pastilles*?
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1. What *BRONCHOSTOP Cough Pastilles* are and what they are used for?

Traditional herbal medicinal product to promote the expectoration of persistent viscous mucus in cough associated with cold.

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

BRONCHOSTOP Cough Pastilles are for adults and adolescents as well as children from 6 years.

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 Pastilles*?

Do not take *BRONCHOSTOP Cough Pastilles*

if you are allergic to thyme herb, 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 Pastilles*.

Talk to your doctor or pharmacist before taking *BRONCHOSTOP Cough Pastilles*, if you have asthma or are prone to allergic reactions. There is a possible risk that this medicine may trigger severe allergic reactions in patients with a history of allergic reactions or asthma. Treatment should be discontinued at the first sign of an allergic reaction (See Section 4 for possible side effects).

Upon the occurrence of fever, shortness of breath or purulent discharge, a doctor should be consulted.

Children

The use in children under 6 years of age is not recommended due to lack of data and because of the risk of unintentionally swallowing the entire pastille.

Other medicines and *BRONCHOSTOP Cough Pastilles*

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

No interaction studies have been performed.

To date 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.

In the absence of sufficient data, the use of this medicinal product 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.

***BRONCHOSTOP Cough Pastilles* contain fructose and sorbitol**

This medicinal product contains 300 mg fructose and 523 mg sorbitol per pastille.

Sorbitol is a source of fructose.

Talk to your doctor before you (or your child) take this medicinal product, if your doctor has advised you (or your child) to have an intolerance to some sugars or if you have a hereditary fructose intolerance (HFI), a rare congenital disorder in which fructose cannot be broken down, was found.

Sorbitol can cause gastrointestinal discomfort and can have a mild laxative effect.

Note for diabetics: One pastille corresponds to approximately 0.1 carbohydrate units.

***BRONCHOSTOP Cough Pastilles* contain propylene glycol, benzyl alcohol and sodium**

This medicinal product contains 5.53 mg propylene glycol and 0.0018 mg benzyl alcohol.

Benzyl alcohol can cause allergic reactions.

This medicinal product contains less than 1 mmol sodium (23 mg) per pastille, that is to say essentially "sodium-free".

3. How to take *BRONCHOSTOP Cough Pastilles*?

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.

Recommended dosage

Adults and adolescents over 12 years of age:

1 – 2 pastilles every 3 to 4 hours (4 to 6 times per day).

Children between 6 – 11 years of age:

1 pastille 3 times per day.

Method of administration:

For oral use. Allow to dissolve in the mouth by sucking.

Duration of administration:

Self-medication with *BRONCHOSTOP Cough Pastilles* should be limited to five days.

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

Use in children

The use in children under 6 years of age is not recommended due to lack of data and because of the risk of unintentionally swallowing the entire pastille.

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

There are no reported cases due to overdosing of this medicinal product.

If you forget to take *BRONCHOSTOP Cough Pastilles*

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.

This medicine can cause the following serious allergic reactions. If you experience any of the following side effects, stop taking this medicine immediately and seek medical advice:

- Sudden and severe allergic reactions, with breathing difficulty, swelling, lightheadedness, fast heartbeat, sweating and loss of consciousness
- Rapid swelling under the skin in areas such as face, throat, arms and legs
- Difficulty breathing or shortness of breath

Other possible side effects

If any of the following side effects get serious or concern you, or you notice any other side effect, stop taking this medicine and seek medical advice as soon as possible:

- Allergic skin reactions including rash, itching and itchy rash.
- Stomach and gut disorders such as belly pain or discomfort, diarrhoea, vomiting, and nausea.

The frequency of the possible side effects occurring is not known (frequency cannot be estimated from the available data).

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 Pastilles*?

Do not store above 25°C.

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

Keep out of the sight and reach of children.

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

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 help protect the environment.

6. Contents of the pack and other information

What *BRONCHOSTOP Cough Pastilles* contain

The active substance is: thyme herb dry extract

One pastille contains:

59.5 mg thyme herb dry extract (thymi herba, drug-extract ratio = 7-13 : 1; extraction agent: water)

The other ingredients are:

Gum Arabic (gummi arabicum E 414), fructose, sorbitol liquid 70% non-crystallising (E 420), maltodextrin, citric acid (E 330), saccharine-sodium (E 954), aronia (chokeberry) flavour (contains propylene glycol (E 1520), forest berry flavour (contains propylene glycol (E 1520) and benzyl alcohol (E 1519)), paraffin light liquid, purified water

What *BRONCHOSTOP Cough Pastilles* look like and contents of the pack

BRONCHOSTOP Cough Pastilles are hexagonal, brown pastilles with fruity taste.

BRONCHOSTOP Cough Pastilles are sealed into PVC / PE / PVdC - alu blister packs and are available in packages with 20 or 40 pastilles. Not all pack sizes will necessarily be marketed.

Marketing Authorisation Holder and Manufacturer
Kwizda Pharma GmbH, Effingergasse 21, A-1160 Vienna

Reg. no.: HERB-00087

This leaflet was last revised in September 2024.