

Package Leaflet: Information for the user

BRONCHOSTOP duo Cough Pastilles

Thyme herb dry extract, Marshmallow root 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, pharmacist or healthcare practitioner has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist or qualified healthcare practitioner 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 5 days.

What is in this leaflet:

1. What *BRONCHOSTOP duo Cough Pastilles* are and what they are used for
2. What you need to know before you take *BRONCHOSTOP duo Cough Pastilles*?
3. How to take *BRONCHOSTOP duo Cough Pastilles*
4. Possible side effects
5. How to store *BRONCHOSTOP duo Cough Pastilles* contents of the pack and other information.

1. WHAT *BRONCHOSTOP DUO COUGH PASTILLES* ARE AND WHAT THEY ARE USED FOR?

Traditional herbal medicinal product used to relieve tussive irritation and to promote the expectoration of persistent, viscous mucus in coughs associated with cold.

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

BRONCHOSTOP duo Cough Pastilles are for adults, adolescences and children from 4 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 duo Cough Pastilles?*

Do not take *BRONCHOSTOP duo Cough Pastilles*

If you are hypersensitive (allergic) to thyme herb, marshmallow root or to other members of the Lamiaceae family or to any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

If you are prone to asthma and allergic reactions, contact your doctor or pharmacist before taking *BRONCHOSTOP duo Cough Pastilles*.

There is a possibility that this medicine may cause severe allergic reactions in patients with a history of such reactions. Treatment should be stopped at the first sign of an overreaction (see section 4 for possible side effects). In the case of shortness of breath, fever or purulent discharge, a doctor must be consulted.

The uptake of medications given at the same time may be delayed. As a precautionary measure, *BRONCHOSTOP duo Cough Pastilles* should therefore be taken ½ to 1 hour before or after taking other drugs.

Children

The use in children under 4 years of age is not recommended due to the lack of data and the risk of unintentionally swallowing the entire pastille.

Other medicines and *BRONCHOSTOP duo Cough Pastilles*

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

No interaction studies have been performed. So far, no interactions have become known.

Pregnancy, breast-feeding and fertility

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, use during pregnancy or breast-feeding is not recommended.

Driving and using machines

No studies have been performed on the effects on the ability to drive or to use machines.

***BRONCHOSTOP duo Cough Pastilles* contain maltitol and sorbitol**

This medicinal product contains 615 mg maltitol and 210 mg sorbitol per pastille. Sorbitol is a source of fructose. Talk to your doctor before you (or your child) take or receive this medicine, if your doctor has told you (or your child) has an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI) - a rare congenital disease in which a person cannot break down fructose.

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

***BRONCHOSTOP duo Cough Pastilles* contain Propylene glycol, Benzyl alcohol and Sodium**

This medicine contains 6.42 mg propylene glycol and 0.005 mg benzyl alcohol per pastille. Benzyl alcohol can cause allergic reactions.

This medicine contains less than 1 mmol sodium (23 mg) per pastille, which means that it is essentially 'sodium-free'.

3. HOW TO TAKE *BRONCHOSTOP DUO COUGH PASTILLES*

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, elderly and children from 12 years of age:

2 pastille every 3 to 4 hours (4 to 6 times per day; Maximum daily dose is 12 pastilles)

Use in children

Children between 4 – 11 years of age:

1 pastille every 3 to 4 hours (4 to 6 times per day; Maximum daily dose is 6 pastilles)

Method of administration:

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

Duration of administration:

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

The use in children under 4 years of age is not recommended due to a lack of data and the risk of accidentally swallowing the entire pastille.

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

There are no known cases of overdose.

If you forget to take *BRONCHOSTOP duo 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, *BRONCHOSTOP duo Cough Pastilles* can cause adverse effects, although not everybody gets them.

This medicine may cause the following serious allergic reactions:

- Sudden and severe allergic reactions with difficulty breathing, swelling, dizziness, fast heartbeat, sweating, and loss of consciousness
- Sudden swelling under the skin in the face, neck, arms, and legs
- Difficulty breathing or shortness of breath

If you notice any of the side effects listed above, stop taking this medicine immediately and seek medical attention.

Other possible side effects

If any of the following side effects are serious or worry you, or if you notice any other side effects, stop taking this medicine and seek medical attention as soon as possible:

- Allergic skin reactions including rash, itching, and itchy rash
- stomach and intestinal disorders such as abdominal pain or discomfort, diarrhea, vomiting and nausea

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

Reporting of side effects

If you notice any side effects, talk to your doctor or pharmacist. This also applies to adverse 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 WIEN
ÖSTERREICH
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 DUO COUGH PASTILLES*

Do not store above 30°C.

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 blister and the carton after “Use by”. 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 duo Cough Pastilles* contain

One pastille contains:

The active substances are:

Thyme herb dry extract, Marshmallow root extract

51.1 mg thyme herb dry extract (Thymi herba, drug-extract ratio = 7-13 : 1; extraction agent: water) and 4.5 mg marshmallow root dry extract (Althaeae radix, drug-extract ratio = 7-9 : 1; extraction agent: water)

The excipients are:

Arabic gum (E 414), maltitol liquid (E 965), sorbitol liquid 70% (non-crystallizing) (E 420), maltodextrin, citric acid (E 330), anhydrous, saccharin sodium, chokeberry flavour (contains propylene glycol (E 1520)), fruit of the forest flavour (contains propylene glycol (E1520) and benzyl alcohol (E1519), paraffin light liquid, purified water.

What *BRONCHOSTOP duo Cough Pastilles* look like and contents of the package

BRONCHOSTOP duo Cough Pastilles are brown round pastilles sealed in PVC/PE/PVdC-Alu-blister packaging containing 10, 20, 30 or 40 pastilles. Not all pack sizes will necessarily be marketed.

Marketing Authorisation Holder and Manufacturer

Kwizda Pharma GmbH, Effingergasse 21, 1160 Wien, Austria

Reg. No.: 737030

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