Package Leaflet: Information for the user

BRONCHOSTOP® Duo cough pastilles

Active ingredients: 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?
6. 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 pharyngeal irritation and associated dry cough 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 indication exclusively based upon long-standing use.

BRONCHOSTOP® Duo cough pastilles are for adults, adolescents 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
Talk to your doctor or pharmacist before taking **BRONCHOSTOP® Duo 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).

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 lozenge.

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.

The intake of concomitantly administered medicines may be delayed. As a precautionary measure, the product should not be taken ½ to 1 hour before or after intake of other medicinal products.

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 lozenge. 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 lozenge 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 lozenge. Benzyl alcohol can cause allergic reactions.
This medicine contains less than 1 mmol sodium (23 mg) per lozenge, 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 lozenges every 3 to 4 hours (4 to 6 times per day; Maximum daily dose is 12 lozenges)

Children between 4 – 11 years of age:
1 lozenge every 3 to 4 hours (4 to 6 times per day; Maximum daily dose is 6 lozenges)

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

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.

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 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, diarrhea, 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 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**.

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

- The active substances are: Thyme herb dry extract, Marshmallow root dry extract
One lozenge contains:
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 (E414), maltitol liquid (E 965), sorbitol liquid 70% (non-crystallizing) (E 420), maltodextrin, citric acid, 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 lozenges sealed in PVC/PE/PVdC-Alu-blister packaging containing 10, 20, 30 or 40 lozenges.
Not all pack sizes will necessarily be marketed.

Marketing Authorization Holder & Batch Releaser
Kwizda Pharma GmbH,
Effingergasse 21,1160, Vienna, Austria

Bulk Manufacturing & Packaging
BOLDER ARZNEIMITTEL GmbH & CO KG
Rheinische Allee 11, 50858, Northrhine- Westfalia, Cologne, Germany

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THIS A MEDICAMENT
Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.

• Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
• The doctor and the pharmacist are experts in medicines and their benefits and risks.
• Do not by yourself interrupt the period of the treatment prescribed for you.
• Do not repeat the same prescription without consulting your doctor.
• Keep all medicaments out of reach of children.

Council of Arab Health Ministers,
Union of Arab Pharmacists