

Package leaflet: Information for the user

BRONCHOSTOP® DUO Cough Syrup

Thyme herb 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 a doctor if you do not feel better or if you feel worse after 5 days.

If the symptoms persist during the use of the medicinal product or if adverse effect not mentioned in the package leaflet occur, a doctor should be consulted.

What is in this leaflet

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2. What you need to know before you take BRONCHOSTOP® DUO Cough Syrup
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1. WHAT BRONCHOSTOP® DUO COUGH SYRUP IS AND WHAT IT IS USED FOR

BRONCHOSTOP® DUO Cough Syrup is a 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 Syrup is indicated in adults, adolescents and children from 2 years of age. Children between 2 and 3 years of age should use this product only upon doctor's recommendation.

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 SYRUP

Do not take BRONCHOSTOP® DUO Cough Syrup if you are allergic to Marshmallow root, Thyme, to other plants of the Lamiaceae family or 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 Syrup

– if you have asthma or are prone to develop allergic reactions, as BRONCHOSTOP® DUO Cough Syrup may make asthma symptoms worse. There is a possible risk that this medicine may trigger allergic reactions, in very rare cases anaphylaxis including anaphylactic shock, in patients who have a tendency to develop allergic reactions.

If fever, shortness of breath or purulent discharge occurs, a doctor should be consulted.

Children

Children under 4 years

In children aged between 2 – 3 years the product should only be used after consultation with a doctor.

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® DUO Cough Syrup

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

Ascorbic acid (contained as excipient) may interfere with other medicines that you may be taking. Tell your doctor if you are taking any of the following: iron-containing medicines, antacids.

No interactions with other medicinal products are known.

Interference with laboratory tests

Talk to your doctor or pharmacists before taking BRONCHOSTOP® DUO Cough Syrup if you are to undergo any blood or urine tests as ascorbic acid can interfere with some blood and urine tests.

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.

There are no data on the effects of this medicine on human fertility as well as during pregnancy and lactation. In the absence of sufficient data, the use during pregnancy and breast-feeding is not recommended.

Driving and using machines

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

Contains no ingredients that are known to cause drowsiness.

BRONCHOSTOP® DUO Cough Syrup contains ascorbic acid as excipient:

This medicine contains 100 mg of ascorbic acid in each 15 ml.

Talk to your doctor or pharmacist before taking BRONCHOSTOP® DUO Cough Syrup

– if you suffer from severe kidney dysfunction and are a dialysis patient: you should not take more than 50 to 100 mg of ascorbic acid per day, as otherwise high oxalate concentrations in the blood (hyperoxalataemia) and resulting formation of oxalate crystals in the kidneys (kidney stones) may occur.

– if you have a tendency to kidney or urinary stones or you have a history of multiple kidney stones, you should not take more than 100 to 200 mg of ascorbic acid daily.

– if you have specific diseases (haemochromatosis, thalassemia and sideroblastic anaemia): ascorbic acid increases iron absorption, therefore its use in high doses can be dangerous.

BRONCHOSTOP® DUO Cough Syrup contains methyl-4-hydroxybenzoate and propyl-4-hydroxybenzoate. These may cause allergic reactions (possibly delayed).

BRONCHOSTOP® DUO Cough Syrup contains propylene glycol.

This medicine contains 96.8 mg of propylene glycol in each 15 ml.

BRONCHOSTOP® DUO Cough Syrup contains sodium. 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® DUO COUGH SYRUP

Always take this medicine exactly as described in this 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.

Use in 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.

Method of administration

For oral use.

Take BRONCHOSTOP® DUO Cough Syrup undiluted, by putting the above-mentioned dose into the enclosed measuring cup which has a 2.5 ml to 20 ml scale.

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

Duration of use

Self-medication with BRONCHOSTOP® DUO Cough Syrup should be limited to 5 days.

If the symptoms persist after 5 days during the use of the medicinal product, a doctor should be consulted.

If you are short of breath, have a high temperature (fever), your phlegm is yellow- green or brown in colour (purulent sputum), you must consult your doctor or qualified healthcare practitioner.

If you take more BRONCHOSTOP® DUO Cough Syrup than you should

No case of overdose has been reported.

If you have taken a considerable overdose of this medicinal product, symptoms of known undesirable effects may occur more intensively.

Additionally, due to the ascorbic acid contained in the product as excipient, complaints such as gastrointestinal complaints (for instance diarrhoea, nausea, vomiting, etc.), disintegration of red blood cells (especially in patients with glucose-6-phosphate dehydrogenase deficiency), kidney stone formation and renal dysfunction up to and including renal failure can occur in case of an overdose.

If an overdose is suspected, please notify your doctor. If necessary, he/she can make a decision on any measures required.

If you forget to take BRONCHOSTOP® DUO 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.

The frequency of the following side effects occurring is not known.

This medicine may cause the following serious allergic reactions. If you experience any of the following effects, stop taking the medicine and seek urgent medical advice:

- symptoms that may include feeling lightheaded or faint, breathing difficulties or wheezing, a fast heartbeat, skin rash, confusion and anxiety, or loss of consciousness (anaphylactic reaction)
- swelling of the face, lips, tongue, mouth or throat (angioedema),
- blistering of the mouth and throat
- difficulty breathing (including 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 the medicine and seek medical advice as soon as possible:

Allergic skin reactions including urticaria (red bumps on the skin), and itching.

Gastrointestinal disorders such as pain or discomfort in the abdomen, diarrhoea, vomiting, and nausea.

Side effect associated with ascorbic acid (contained as excipient): When used as directed, no side effects are generally to be expected.

Very rarely or with unknown frequency, disintegration of red blood cells (haemolysis, especially in patients with glucose-6-phosphate dehydrogenase deficiency), diarrhoea (at high doses), kidney stones and hypersensitivity reactions have been reported.

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.

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

5. HOW TO STORE BRONCHOSTOP® DUO COUGH SYRUP

Keep this medicine out of the sight and reach of children. Do not store above 30 °C . Do not use this medicine after the expiry date which is stated on the carton after "EXP". The expiry date refers to the last day of that month.

Keep the bottle tightly closed after use.

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® DUO Cough Syrup contains

The active substances are:

15 ml of the oral solution contain:

0.12 g of extract (as dry extract) from *Thymus vulgaris* L. and *Thymus zygis* L., herba (*Thymi herba*) (7-13:1). Extraction solvent: water.

0.83 g of extract (as liquid extract) from *Althaea officinalis* L., radix (*Althaeae radix*) (1:12-14). Extraction solvent: water.

The other ingredients are:

maltodextrin
acacia (*gummi arabicum*)
xylitol (E967)
xanthan gum
citric acid monohydrate (E330)
methyl-4-hydroxybenzoate (E218)
propyl-4-hydroxybenzoate (E216)
raspberry flavour (contains propylene glycol (E1520))
malic acid (E296)
ascorbic acid (E300)
neohesperidin-dihydrochalcone
saccharin sodium (E954)
glycerol, anhydrous (E422)
purified water

What BRONCHOSTOP® DUO Cough Syrup looks like and contents of the pack

BRONCHOSTOP® DUO Cough Syrup is a beige, viscous liquid with the scent and taste of thyme and raspberries.

Because of the natural ingredients flocculation, precipitation and turbidity may occur, which does not have a negative impact on the quality of the product.

It is filled into brown glass bottles with a sealed screw cap, in 120 ml, 200 ml, 240 ml and 290 ml sizes.

Not all pack sizes may be marketed.

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

Marketing Authorization Holder & Manufacturer

Kwizda Pharma GmbH,
Effingergasse 21,
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Austria

This leaflet was last revised in April 2023

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.