

BRONCHO STOP®

INSTRUCTIONS FOR USE

CHILDREN'S COUGH SYRUP

Bronchostop Children's Cough Syrup 120 mL

 Read this information carefully before you start using **BRONCHOSTOP CHILDREN'S COUGH SYRUP**.

DO NOT THROW THIS LEAFLET AWAY! It contains important information. If you have any questions about **BRONCHOSTOP CHILDREN'S COUGH SYRUP** please ask your pharmacist or healthcare provider.

What is in this leaflet

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1. What is **BRONCHOSTOP CHILDREN'S COUGH SYRUP** and what is it used for?

BRONCHOSTOP CHILDREN'S COUGH SYRUP is a medical device.

The natural ingredients honey and marshmallow dry root extract cover the inflamed pharyngeal mucosa, forming a physical protective coating against foreign particles, thus relieving irritation from dry or chesty coughs associated with colds, allowing the mucosa to recover.

It is well tolerated and therefore suitable for children.

BRONCHOSTOP CHILDREN'S COUGH SYRUP is suitable for day and night time use. Through its soothing effect it helps ensure a peaceful and restorative sleep.

2. What does **BRONCHOSTOP CHILDREN'S COUGH SYRUP** contain?

Each 5 mL syrup contains
48 mg Marshmallow dry root extract
250 mg Honey

Preservatives: Methyl-4-hydroxybenzoate
Propyl-4-hydroxybenzoate

Contains sugar: Glycerol: 128,3 mg and Xylitol 920 mg

Other ingredients include citric acid, purified water, strawberry aroma and xanthan.

BRONCHOSTOP CHILDREN'S COUGH SYRUP is alcohol free, lactose free, gluten free, and free of genetically modified organisms and artificial colours.

3. What you need to know before you use **BRONCHOSTOP CHILDREN'S COUGH SYRUP**:

Do not take **BRONCHOSTOP CHILDREN'S COUGH SYRUP**:

If you are allergic to marshmallow or honey or to any of the other ingredients of this medical device listed in section 2. In case of an allergic reaction, please discontinue the use of the product and consult your doctor.

BRONCHOSTOP CHILDREN'S COUGH SYRUP contains honey, glycerol and xylitol which may have an effect on the control of blood sugar in children with *diabetes mellitus*. Xylitol may have a laxative effect.

Warning and precautions

Use in patients with intolerances to sugars

Patients with rare hereditary fructose intolerance or glucose-galactose malabsorption should not take this product as it contains honey.

Please consult a doctor if: fever, shortness of breath, or discoloured sputum occurs during the use of **BRONCHOSTOP CHILDREN'S COUGH SYRUP**.

Use in patients with diabetes

15 mL **BRONCHOSTOP CHILDREN'S COUGH SYRUP** contains 0,3 CU (carbohydrate units)

Use in pregnancy and breastfeeding

BRONCHOSTOP CHILDREN'S COUGH SYRUP is not recommended for use during pregnancy or breastfeeding.

Use in children

Use in children under 1 year of age is not recommended. Children under 3 years of age should consult with a doctor to exclude more serious diseases being present.

Taking other medicines with **BRONCHOSTOP CHILDREN'S COUGH SYRUP**

If you take other medicines it is advised to take them ½ hour to 1 hour before or after intake of **BRONCHOSTOP CHILDREN'S COUGH SYRUP**.

If you are taking medicines on a regular basis, including medicines bought over the counter and complementary or traditional medicines, the use of **BRONCHOSTOP CHILDREN'S COUGH SYRUP** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist, or other healthcare professional for advice.

Should symptoms persist or your child's general health worsen after 5 days, please consult your doctor, pharmacist, or other healthcare professional for advice.

4. How to use **BRONCHOSTOP CHILDREN'S COUGH SYRUP**

Always administer **BRONCHOSTOP CHILDREN'S COUGH SYRUP** exactly as your doctor or healthcare provider has instructed. You should check with your doctor or healthcare provider if you are unsure.

Use the measuring cup provided to administer the required dose.

Children 1 – 3 years: 5 mL up to 3 times a day

Children 4 – 5 years: 7,5 mL up to 4 times a day

Children 6 - 11 years: 15 mL up to 4 times a day

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BRONCHOSTOP CHILDREN'S COUGH SYRUP can be taken during the day and at night.

BRONCHOSTOP CHILDREN'S COUGH SYRUP can be taken by children with lactose or gluten intolerance or sensitivity.

BRONCHOSTOP CHILDREN'S COUGH SYRUP is not recommended for use in children under 1 year.

You must consult your doctor if your child does not feel better or if they feel worse after 5 days.

If you are unsure or have any questions, consult your doctor or pharmacist.


5. Possible Side Effects



The following side effects are known:

BRONCHOSTOP CHILDREN'S COUGH SYRUP contains methyl-4-hydroxybenzoate and propyl-4-hydroxybenzoate as preservatives. These may cause allergic reactions (possibly delayed).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. Storing and Disposing of BRONCHOSTOP CHILDREN'S COUGH SYRUP

 ^{25°C} Keep this medical device out of the sight and reach of children. Store the bottle in the original package, in a cool, dry place at or below 25 °C. Close the bottle tightly after use. Protect from sunlight and moisture. After opening the bottle, use within 4 weeks.

-  Do not use this product after the expiry date stated on the label and carton.
-  Return all unused medical device to your pharmacist. Do not dispose of unused medical device in drains or sewerage systems (e.g. toilets).

7. Content of BRONCHOSTOP CHILDREN'S COUGH SYRUP

BRONCHOSTOP CHILDREN'S COUGH SYRUP is a brown liquid. The natural ingredients can lead to the formation of fine particles and the colour may vary from light to dark brown. These possible variations do not affect the quality of the syrup in any way.

It is filled in brown glass bottles with original sealed screw cap to 120 mL, 200 mL and 240 mL.

Not all pack sizes may be marketed. The enclosed measuring cup with a scale between 2.5 mL and 20 mL facilitates an exact dosage of the recommended amount.

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Production:

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