

Package leaflet: Information for the user

## Bronchostop® Night oral solution

Marshmallow root dry extract  
Lime flower dry extract  
Ribwort plantain 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 have 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 7 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 or pharmacist should be consulted.

### What is in this leaflet

- 1.What Bronchostop® Night oral solution is and what it is used for
- 2.What you need to know before you take Bronchostop® Night oral solution
- 3.How to take Bronchostop® Night oral solution
- 4.Possible side effects
- 5.How to store Bronchostop® Night oral solution
- 6.Contents of the pack and other information

### 1.What Bronchostop® Night oral solution is and what it is used for

The polysaccharides contained in marshmallow root and ribwort plantain relieve oral or pharyngeal irritation and thus the urge to cough during the day as well as during the night. The ingredients of lime flower promote sweating and thereby relieve feverish colds.

Bronchostop Night oral solution is a traditional herbal medicinal product for the relief of dry cough as well as night-time cough, pharyngeal irritation and promotion of sweating during (low-grade) fever as early symptoms of a common cold.

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

You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

### 2.What you need to know before you take Bronchostop® Night oral solution

#### Do not take Bronchostop® Night oral solution

- if you are allergic to marshmallow root, lime flower or ribwort plantain 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® Night oral solution.

If the symptoms worsen during the use of the medicinal product or if dyspnoea, high fever or purulent sputum occurs, a doctor should be consulted.

Absorption of concomitantly administered medicines may be delayed. As a precautionary measure, this medicinal product should not be taken 30 minutes to 1 hour before or after taking other medicines.

#### Children

The use in children under 4 years of age has not been established due to lack of adequate data.

#### Other medicines and Bronchostop® Night oral solution

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

Interactions are not known.

No interaction studies have been performed.

#### Bronchostop® Night oral solution with food and drink

Due to the way in which this medicine works (partly physical and local), it is recommended not to drink and/or eat for 30 minutes to 1 hour after intake.

#### 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.

Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

#### Driving and using machines

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

#### Bronchostop® Night oral solution contains xylitol

This medicine contains 11.04 g xylitol in the maximum daily dose (60 ml). It may therefore have a laxative effect. Calorific value is 2.4 kcal/g xylitol.

#### Bronchostop® Night oral solution contains methyl- parahydroxybenzoate and propyl-parahydroxybenzoate

These preservatives may cause hypersensitivity (allergic) reactions, possibly delayed.

#### Bronchostop® Night oral solution contains 13.6 mg propylene-glycol and 0.002 mg benzyl alcohol

Benzyl alcohol may cause allergic reactions.

#### 3.How to take Bronchostop® Night oral solution

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.

Start at the early signs of common cold.

The recommended dose is:

*Adults and adolescents aged 12 years and above:*

15 ml (the measuring cup provided) up to 4 times daily (maximum daily dose up to 60 ml). The last dose should be taken directly before bedtime.

*Paediatric population*

Children from 4 to 11 years of age:

7.5 ml (using the measuring cup provided) 3 to 4 times daily (maximum daily dose up to 30 ml). The last dose should be taken directly before bedtime.

#### Method of administration

For oral use.

The medicinal product is taken undiluted. It is recommended not to drink and/or eat for 30 minutes to 1 hour after intake.

A measuring cup is provided.

#### Duration of use

If the symptoms worsen or persist longer than 7 days during the use of the medicinal product, a doctor or a qualified healthcare practitioner should be consulted.

#### Use in children

Due to lack of adequate data the use in children below 4 years is not recommended.

#### If you take more Bronchostop® Night oral solution than you should

No cases of overdose have been reported.

#### If you forget to take Bronchostop® Night oral solution

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.

No side effects are known.

#### 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® Night oral solution

Do not store above 30 °C.

Keep the container tightly closed after use. Keep in original packaging in order to protect from light.

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 carton and on the bottle label {abbreviation used for expiry date}. The expiry date refers to the last day of that month.

After opening, use within 2 months.

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® Night oral solution contains

-The active substances are:

15 ml (= 16.3 g) oral solution contains:

- 187.5 mg of extract (as dry extract) from *Althaea officinalis* L., radix (Marshmallow root) DER (7-9:1). Extraction solvent: water.
- 136.4 mg of extract from (as dry extract) *Tilia cordata* Miller, *Tilia platyphyllos* Scop., *Tilia x vulgaris* Heyne or their mixtures, flos (Lime flower) DER (3-8:1). Extraction solvent: water.
- 150.0 mg of extract (as dry extract) from *Plantago lanceolata* L., folium (Ribwort plantain) DER (4-6:1). Extraction solvent: water.

-The other ingredients are:

- Xylitol (E 967)
- Maltodextrin
- Glycerol
- Xanthan gum
- Citric acid monohydrate
- Strawberry flavour (contains benzyl alcohol (E 1519) and propylene-glycol (E 1520)),
- Methyl-parahydroxybenzoate (E218)
- Silica colloidal anhydrous
- Propyl-parahydroxybenzoate (E216)
- Purified water

#### What Bronchostop® Night oral solution looks like and contents of the pack

Bronchostop® Night oral solution is a brown, opaque oral solution. It is filled into brown glass bottles sealed with a screw cap and packed in carton box. The enclosed measuring cup with a scale between 2.5 ml and 20 ml facilitates precise measuring of the recommended amount.

Bronchostop® Night oral solution is available in 120 ml, 200 ml and 240 ml pack sizes. Not all pack sizes will necessarily be marketed.

#### Marketing Authorisation Holder and Manufacturer

Kwizda Pharma GmbH

Effingergasse 21

1160 Vienna

Austria

This leaflet was last revised in Feb. 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.