

## **Package leaflet: Information for the patient**

### **BRONCHOSTOP NITE 187.5 mg/136.4 mg/150 mg oral solution**

Active substances: 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 5 days (3 days in children).

### **What is in this leaflet**

1. What BRONCHOSTOP NITE is and what it is used for
2. What you need to know before you take BRONCHOSTOP NITE
3. How to take BRONCHOSTOP NITE
4. Possible side effects
5. How to store BRONCHOSTOP NITE
6. Contents of the pack and other information

#### **1. What BRONCHOSTOP NITE 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.

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.

BRONCHOSTOP NITE is indicated for use in adults, adolescents and children from 4 years of age.

You must talk to a doctor if you do not feel better or feel worse after 5 days (3 days in children).

#### **2. What you need to know before you take BRONCHOSTOP NITE**

##### **Do not take BRONCHOSTOP NITE**

- 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 NITE.

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 NITE**

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

Interactions are not known.

No interaction studies have been performed.

### **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 NITE 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 2.4 kcal/g xylitol.

### **BRONCHOSTOP NITE contains methyl-4-hydroxybenzoate and propyl-4-hydroxybenzoate**

These preservatives may cause allergic reactions (possibly delayed).

### **BRONCHOSTOP NITE contains propylene-glycol and benzyl alcohol**

This medicine contains 13.6 mg propylene-glycol and 0.002 mg benzyl alcohol per single dose (15 ml). Benzyl alcohol may cause allergic reactions.

## **3. How to take BRONCHOSTOP NITE**

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 from 12 years of age:*

15 ml (using 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.

*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.

BRONCHOSTOP NITE is taken undiluted. It is recommended to avoid drinking and/or eating for 30 minutes to 1 hour after intake.

A measuring cup is provided.

Duration of use:

If the symptoms worsen or persist longer than 5 days (3 days in children) during the use of the medicinal product, a doctor 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 NITE than you should**

No cases of overdose have been reported.

#### **If you forget to take BRONCHOSTOP NITE**

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 listed in Appendix V](#).\* By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store BRONCHOSTOP NITE**

After opening, do not store above 25 °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 after {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 NITE 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) (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) (3-8:1). Extraction solvent: water.
- 150.0 mg of extract (as dry extract) from *Plantago lanceolata* L., folium (Ribwort plantain) (4-6:1). Extraction solvent: water.

- The other ingredients are:  
Maltodextrin, silica colloidal anhydrous, glycerol, xylitol (E 967), methyl-4-hydroxybenzoate (E 218), propyl-4-hydroxybenzoate (E 216), citric acid monohydrate, xanthan gum, strawberry flavour (contains benzyl alcohol (E 1519), propylene-glycol (E 1520)), water, purified

#### **What BRONCHOSTOP NITE looks like and contents of the pack**

BRONCHOSTOP NITE is a brown, opaque oral solution. It is filled into brown glass bottles sealed with a screw cap in 120 ml, 200 ml and 240 ml pack sizes. Not all pack sizes will necessarily be marketed.

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

#### **Marketing Authorisation Holder and Manufacturer**

Marketing Authorisation Holder: Oktal Pharma d.o.o, Utinjska 40, 10020 Zagreb, Republic of Croatia

Manufacturer: Kwizda Pharma GmbH, Effingergasse 21, 1160 Vienna, Austria

**This leaflet was last revised in May 2021**