### **APPROVED**

by order of chairman of Committee of medicinal and pharmaceutical activities of Ministry of Healthcare of Republic of Kazakhstan

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# INSTRUCTION for medical use of medicinal product BRONCHOSTOP® Syrup

Trade name

Bronchostop® Syrup

## International nonproprietary name

No

### Dosage form

Syrup 120 ml

## **Composition**

1 ml of syrup contains *active ingredients:* thyme herb dry extract 8.0 mg, marshmallow root liquid extract 55.3 mg, *excipients:* 

maltodextrin, acacia, raspberry juice, xylitol, xanthan gum, citric acid's monohydrate, methyl parahydroxybenzoate (E 218), propyl parahydroxybenzoate (E 216), raspberry flavouring, purified water.

During manufacturing process of thyme herb dry extract (ratio of raw material to extraction solvent 7-13:1), marshmallow root liquid extract (ratio of raw material to extraction solvent 1:12-14) water was used like extraction solvent.

# **Appearance**

Viscous, brown liquid with characteristic odour (thyme).

# Pharmacotherapeutic group

Cough and cold preparations.

Expectorants.

Expectorants combinations.

ATC code: R05C A10

## Pharmacological properties Pharmacokinetics

Not required.

### **Pharmacodynamics**

Thyme has secretolytic, expectorative and broncholytic properties and supports the expectoration of viscous mucus. The essential oil, which is contained in the thyme herb extract, has antiseptic properties.

Polysaccharides from marshmallow roots relieve irritation of mucous membranes by building a protective layer. This increases the barrier to irritants and reduces the sensitivity of the cough receptors thereby reducing the urge to cough.

#### **Indications**

- as a demulcent to relieve irritation of the throat and as an expectorant in cough associated with cold of upper breathing passages.

### Method of administration and doses

For oral use, undiluted.

If required, Bronchostop<sup>®</sup> Syrup may be may be diluted in water or warm tea.

Adults and adolescents over 12: 15 ml every 3-4 hours (4-6 times per day; maximum daily dose up to 90 ml).

<u>Children between 4 - 12:</u> 7.5 ml every 3-4 hours (4-6 times per day; maximum daily dose up to 45 ml).

Children between 2-4: after consultation with doctor may be used 7.5 ml every 3-4 hours (4-6 times per day; maximum daily dose up to 45 ml).

<u>Children under 2 years:</u> administration in children under 2 years is not recommended. Duration of treatment with product Bronchostop<sup>®</sup> Syrup should be limited to five days. If in 5 days no improvement has occurred it is necessary to consults a doctor.

#### **Undesirable effects**

- hypersensitivity reactions (including one case of anaphylactic shock and one case of Quincke's oedema)
- stomach disorders have been observed in connection with medicinal products containing thyme.

#### **Contraindications**

- hypersensitivity to the active substances, to other members of the Lamiaceae family or to any of the excipients,
- children under 2 years,
- hereditary fructose intolerance.

### Interaction with other medicinal products or other forms of interaction.

No drug interaction studies have been performed.

### **Special warnings**

When dyspnoea, fever, purulent sputum and/or appearance of undesirable effects occur a doctor should be consulted.

Bronchostop<sup>®</sup> Syrup contains methylparahydroxybenzoate and propylparahydroxybenzoate preservatives. These may cause hypersensitivity reactions, including delayed reactions.

Administration in children under 2 years is not recommended due to lack of sufficient data.

Pregnancy and lactation.

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

Effects on ability to drive and to use machines.

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

#### **Overdose**

Symptoms: intensification of undesirable effects.

*Treatment*: cancelation of product, if necessary – symptomatic treatment.

## Package and presentation

120 ml of solution in brown-glasses flacons, with nozzle and polyethylene screw cap with temper-proof.

1 flacon with polypropylene measured glass with scale from 2.5 ml to 20 ml with instruction for medical use of medicinal product in state and Russian languages in carton box.

## **Storage conditions**

To store below 25°C in place protected from light.

Keep out of reach of children!

### Shelf life

3 years

Store 4 weeks after first opening of the flacon.

Do not use the medicine after expiry date.

# Release category

Without prescription

#### Manufacturer

Kwizda Pharma GmbH,

Effingergasse 21, 1160 Vienna, Austria.

# Manufacturing authorization holder

Kwizda Pharma GmbH,

Effingergasse 21, 1160 Vienna, Austria.

Address of the entity receiving the complaints from consumers on the quality of products (goods) on the territory of the Republic of Kazakhstan:

Representative office of Delta Medical Promotions AG (Switzerland)

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