

APPROVED

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

“ ” _____ 201 _____

N _____

**INSTRUCTION for medical use
of medicinal product
BRONCHOSTOP® Pastilles**

Trade name

Bronchostop® Pastilles

International nonproprietary name

No

Dosage form

Pastilles

Composition

One pastille (2 g) contains

active ingredient: thyme herb dry extract 59.5 mg,

excipients: maltodextrin, acacia, fructose, sorbitol solution 70% non crystallizing (E 420), citric acid anhydrous, sodium saccharin (E 954), chokeberry flavoring, berry flavoring, paraffin liquid, paraffin liquid, purified water.

During manufacturing process of thyme herb dry extract (ratio of raw material to extraction solvent 7 – 13 : 1) water was used like extraction solvent.

Appearance

Pastilles of hexagonal shape, brown colour with fruity taste.

Pharmacotherapeutic group

Cough and cold preparations.

Expectorants.

ATC code R05C A

Pharmacological properties

Pharmacokinetics

Not required.

Pharmacodynamics

Extract of 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.

Indications.

- an expectorant in cough associated with cold of upper air passages.

Method of administration and doses

For oral use.

Adults and adolescents over 12:

When necessary 1-2 pastilles must be consecutively dissolved each 3-4 hours per day (4-6 times per day).

Children between 6 - 12:

When necessary 1 pastille must be dissolved each 3-4 times per day (4-6 times per day).

If in 7 days no improvement has occurred it is necessary to consult a doctor.

Undesirable effects

- hypersensitivity reactions (including one case of anaphylactic shock and one case of Quincke's oedema)

- stomach disorders.

The frequency is not known.

Contraindications

- hypersensitivity to the active substances, to other members of the Lamiaceae family or to any of the excipients

- hereditary intolerance of fructose, malabsorption of glucose and galactose

- pregnancy and lactation

- children with age under 6 years.

Interaction with medicinal products

No interaction studies have been performed.

Special warnings

Due to lack of data and because of the risk of unintentionally swallowing the entire pastille, the use in children under 6 years of age is not recommended.

Products contain fructose, sorbitol, saccharine. Patients who suffer from the rare hereditary fructose intolerance should not apply Bronchostop Pastilles.

In case of deterioration the development of breathing, temperature rise or the appearance of purulent sputum, you need to see a doctor.

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

No case of overdose has been reported.

Package and presentation

10 pastilles hermetically packed in contour-cellular package from PVC/PE/PVDC and aluminum foil.

2 contour packages with instruction for medical use in state and Russian languages in the carton box.

Storage conditions

Do not store above 25°C in place protected from light.

Keep out of reach of children!

Shelf life

3 years

Do not use the medicine after expiry date.

Release category

Without prescription

Manufacturer

Bolder Arzneimittel GmbH & Co. KG

Rheinische Allee 11, 50858 Koln, Germany.

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)

050040, Almaty, Bostandyk district, st. Baizakov, d.280

Tel. / fax: +7 (727) 332 20 79

E-mail: PVG@deltamedical.com.ua