

PACKAGE LEAFLET: INFORMATION FOR THE USER

Bronchostop[®] sine sirup, syrup

Read whole 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 has 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 of the 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 your doctor if you do not feel better or if you feel worse after seven days.

What is in this leaflet

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

1. What Bronchostop sine sirup is and what it is used for

Medicinal product Bronchostop sine syrup contains a dry extract of the herb thyme (*Thymus vulgaris* L. or *Thymus zygis* L.) and a liquid extract of the root of marshmallow (*Althaea officinalis* L.).

Medicinal product Bronchostop sine sirup is traditional herbal medicinal product used to relieve irritation of the throat and to promote the expectoration in cough associated with cold.

The medicinal product is a traditional herbal medicinal product which use is based upon long-standing experience exclusively.

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

2. What you need to know before you take Bronchostop sine sirup

Do not take Bronchostop sine sirup

if you are allergic (hypersensitive) to active substance (thyme, marshmallow) or to other members of the *Lamiaceae* family or to any of the excipients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Bronchostop sine sirup if you have asthma or are prone to develop allergic reactions, as Bronchostop sine sirup may make asthma symptoms worse. There is a possible risk that this medicine may trigger allergic reactions, in very rare cases anaphylaxis including anaphylactic shock, in patients who have a tendency to develop allergic reactions. In the case of fever, shortness of breath or purulent discharge, a doctor should be consulted.

Children

Children under 12 years

The use in children under 12 years of age is not recommended due to lack of data about use in this population, therefore you need to consult your child's doctor.

Other medicines and Bronchostop sine sirup

Tell your doctor or pharmacist if you are taking / using, have recently taken / used or might take / use any other medicines, including medicines you can buy without prescription.

No interactions with other medicinal products are known. Resorption of concomitantly administered medicines may be delayed. As a precautionary measure, the product should not be taken ½ to 1 hour before or after intake of other medicinal products.

Pregnancy, breast-feeding and fertility

There are no data on the influence of this medicine on fertility, during pregnancy and breast-feeding. In the absence of adequate data, the use of this medicine during pregnancy and breast-feeding is not recommended.

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.

Driving and using machines

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

Medicinal product Bronchostop sine sirup contains the preservatives methyl-parahydroxybenzoate and propyl-parahydroxybenzoate. These may cause allergic reactions which may also appear as a delayed reaction (see section Do not take Bronchostop sine sirup).

Medicinal product Bronchostop sine sirup contains xylitol.

Xylitol may have a laxative effect. Calorific value 2.4 kcal/g xylitol.

Medicinal product Bronchostop sine sirup contains raspberry juice concentrate which contains sucrose, glucose and fructose.

This medicine contains 66 mg fructose in each 15 mL. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary

fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

Medicinal product Bronchostop sine sirup contains propylene glycol.

This medicine contains 33.3 mg of propylene glycol in each 15 mL.

3. How to take Bronchostop sine sirup

Always take this medicine exactly as described in this package leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist, if you are not sure.

If you are short of breath, have a high temperature (fever), your phlegm is yellow-green or brown in colour (purulent sputum), you must consult your doctor or qualified healthcare practitioner.

Dosage:

Adults and children over 12 years of age:

15 mL every 3 to 4 hours (4 to 6 times per day; maximum daily dose is 90 mL).

Children aged less than 12 years :

The use in children under 12 years of age is not recommended due to lack of data and because medical advice should be sought.

Duration of administration:

If symptoms persist longer than a week, the patient is advised to consult a doctor

Method of administration:

Medicine is intended for oral use, undiluted.

If required, you may take Bronchostop sine sirup diluted in water or warm tea.

Take medicine Bronchostop sine sirup undiluted by putting the abovementioned dose into the enclosed measuring cup which has a 2.5 mL to 20 mL scale.

If you take more Bronchostop sine sirup than you should:

If you have taken a considerable overdose of this medicinal product, symptoms of known undesirable effects may occur more intensively. In this case, please notify your doctor. If necessary, he/she can make a decision on any measures required.

If you forget to take Bronchostop sine sirup

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.

The frequency of the following side effects occurring is not known.

This medicine may cause the following serious allergic reactions:

- symptoms that may include feeling lightheaded or faint, breathing difficulties or wheezing, a fast heartbeat, skin rash, confusion and anxiety, or loss of consciousness (anaphylactic reaction)
- swelling of the face, lips, tongue, mouth or throat (angioedema),
- blistering of the mouth and throat
- worsening of asthma symptoms
- difficulty breathing (including shortness of breath)

If you experience any of the following effects, stop taking the medicine and seek urgent medical advice:

Other possible side effects

If any of the following side effects get serious or concern you, or you notice any other side effect, stop taking the medicine and seek medical advice as soon as possible:

Allergic skin reactions including urticaria (red bumps on the skin), and itching.

Disorders of digestive system such as pain or discomfort in the abdomen, diarrhoea, vomiting, and nausea.

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. By reporting of side effects of the medicinal product you can help in evaluation of safety profile of this medicinal product. You can report any suspected adverse reactions via Medicines and Medical Devices Agency of Serbia (ALIMS):

Medicines and Medical Devices Agency of Serbia
National Pharmacovigilance Center
Vojvode Stepe 458, 11221 Beograd
Republika Srbija
fax: +381 (0)11 39 51 131
website: www.alims.gov.rs
e-mail: nezeljene.reakcija@alims.gov.rs

5. How to store Bronchostop sine sirup

Keep out of the sight and reach of children.

Do not use medicine Bronchostop sine sirup after the expiry date which is stated on the carton after "Use by". The expiry date refers to the last day of that month

Shelf life after the first opening: **4 weeks.**

Do not store above 25°C.

Store the bottle in the original package in order to protect the contents from light. Close the bottle firmly after use.

Unused medicines must be submitted to the pharmacy where it was pointed out that this pharmacy collects unused medicines from citizens. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away. These measures help protect the environment.

6. Contents of the pack and other information

What Bronchostop sine sirup contains

Active ingredients are: dry extract of thyme herb (*Thymus vulgaris* L. or *Thymus zygis* L.) and liquid extract of marshmallow root (*Althaea officinalis* L.).

15 mL of syrup (equivalent to 16.7 g) contains:

0,12 g thyme herb dry extract (*Thymus vulgaris* L. ili *Thymus zygis* L.), (7 - 13 : 1), extraction agent: water and

0,83 g marshmallow root liquid extract (*Althaea officinalis* L.), (1 : 13), extraction agent: water (expressed as native extracts).

The other ingredients are:

xylitol (E967), methyl-parahydroxybenzoate (E218), propyl-parahydroxybenzoate (E216), raspberry juice concentrate (containing sucrose, glucose and fructose), raspberry aroma flavour (synthetic and natural flavourings, propylene glycol (E1520)), xanthan gum, citric acid monohydrate, maltodextrin, acacia (E414), water, purified

What Bronchostop sine sirup looks like and contents of the packaging

Medicinal product Bronchostop sine sirup is viscous, brown, liquid with the characteristic smell and taste of thyme and raspberries.

Immediate package is glass bottles (class III), amber (120 mL) with with high density polyethylene nozzle. Screw cap, white, polypropylene.

In the inner package there is transparent plastic measuring cup (graduated: 2,5 mL; 5 mL; 7,5 mL; 10 mL; 12,5 mL; 15 mL i 20 mL).

Outer package is folding carton box containing one bottle with medicine and Patient information leaflet for use of medicinal product.

Marketing authorisation holder and manufacturer

Marketing authorisation holder:

OKTAL PHARMA D.O.O. BEOGRAD, Beograd, Viline vode BB, Beograd-Palilula

Manufacturer:

KWIZDA PHARMA GMBH, Effingergasse 21, Vienna, Austria,

This Patient Information was revised

November, 2022.**General classification for supply:**

Medicine is available without prescription

Marketing authorisation number and date:

515-01-03184-21-001 of 28.11.2022.