

Package leaflet: Information for the user

BRONCHOSTOP® direct oromucosal spray

Active substances: Liquid extract from thyme, liquid extract from sage leaves

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use 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 even feel worse after 7 days.

What is in this leaflet

1. What BRONCHOSTOP direct oromucosal spray is and what it is used for
2. What you need to know before you use BRONCHOSTOP direct oromucosal spray
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1. What BRONCHOSTOP direct oromucosal spray is and what it is used for

Traditional herbal medicinal product used for the symptomatic treatment of inflammations in the mouth or the throat (such as sore throat, hoarseness and difficulty swallowing) associated with common cold.

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

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

2. What you need to know before you use BRONCHOSTOP direct oromucosal spray

Do not use BRONCHOSTOP direct oromucosal spray,

- if you are allergic to thyme or sage or to any other member of the labiates family or to any of the other ingredients of this medicine listed in section 6.
- if you have bronchial asthma or other respiratory diseases that are associated with marked hypersensitivity of the airways, as inhalation can lead to shortness of breath or trigger an asthma attack.

Warnings and precautions

Talk to your doctor or pharmacist before using BRONCHOSTOP direct oromucosal spray.

When shortness of breath, fever or purulent sputum occurs, you should consult a doctor.

- Do not spray into eyes or nose.
- Do not spray into open flames.

Children and adolescents

In the absence of sufficient data, the use in children and adolescents under 18 years of age is not recommended.

Other medicines and BRONCHOSTOP direct oromucosal spray

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

No studies on the interaction of BRONCHOSTOP direct oromucosal spray have been performed.

Taking medicines containing sage may influence the effect of other medicinal products acting via GABA receptors, such as barbiturates and benzodiazepines, even if this has so far not been seen clinically. Therefore, it is not recommended using BRONCHOSTOP direct oromucosal spray concomitantly with these medicines.

Pregnancy, breast-feeding and fertility

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.

In the absence of sufficient data, it is not recommended using BRONCHOSTOP direct oromucosal spray if you are pregnant or breast-feeding.

Driving and using machines

BRONCHOSTOP direct oromucosal spray has no or negligible influence on the ability to drive and use machines.

BRONCHOSTOP direct oromucosal spray contains Ethanol (alcohol)

This medicine contains 75,7 mg of alcohol (ethanol) per each puff. If the mucous membrane is damaged, it can cause a burning sensation. The amount in each puff of this medicine is equivalent to less than 2 ml beer and 1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

Broncophen Aerol contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per puff, that is to say essentially 'sodium-free'.

3. How to use BRONCHOSTOP direct oromucosal spray

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Recommended dose:

Adults:

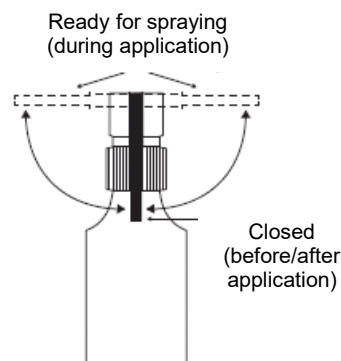
If not prescribed otherwise by your doctor, spray 1 to 2 spray pumps in the mouth and throat, 2 – 4 times per day.

Method of administration

Spray for use in the oral cavity.

The spray allows a uniform and fine distribution of the active ingredients as well as a targeted application at the affected sites.

- Raise the rotatable nozzle on the spray pump at a right angle to the bottle (see figure).
- Direct the spray head towards the desired application site in the mouth. Even sites which are difficult to access (e.g. dental sacs) can be reached easily with the nozzle on the spray pump.
- Spray BRONCHOSTOP direct oromucosal spray on to the painful sites by pressing the pump once or twice. Pump several times before first use in order to obtain a uniform spray pump.
- Close the spray pump after each application by turning the nozzle back (see figure).



Duration of treatment:

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

Children and adolescents

In the absence of sufficient data, the use in children and adolescents under 18 years of age is not recommended.

If you use more BRONCHOSTOP direct oromucosal spray than you should

There are no known cases of thyme overdose. Sage overdose is not possible with this medicine.

If you forget to use BRONCHOSTOP direct oromucosal spray

Do not take double dose to make up for a forgotten dose but continue (as needed) in the manner specified.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Hypersensitivity reactions (including one case of anaphylactic shock and one case of Quincke edema (Swelling of the skin, mucous membrane and adjacent tissue)) and stomach disorders have been observed with thyme-containing medicinal products.

Due to the alcohol content, temporary burning at the inflamed sites may occur.

The frequency of side effects is not known.

Children

BRONCHOSTOP direct oromucosal spray might lead to laryngospasms in infants and children under 2 years, resulting in severe breathing disorders

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:

Austria

Bundesamt für Sicherheit im Gesundheitswesen

Traisengasse 5

1200 VIENNA

AUSTRIA

Fax: + 43 (0) 50 555 36207

Website: <http://www.basg.gv.at/>

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store BRONCHOSTOP direct oromucosal spray

Unopened: do not store above 30 °C.

After first opening do not store above 25 °C.

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 label and carton after “Use by:”. The expiry date refers to the last day of that month.

Shelf life after first opening: 8 weeks.

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 direct oromucosal spray contains:

The active substances are: Liquid extract from thyme herb, liquid extract from sage leaves.

1 g contains:

0.32 g of liquid extract from thyme herb (Thymi herba), drug-extract ratio 1:4 – 6, extraction solvent ethanol (70% V/V)

0.32 g of liquid extract from sage leaf (Salviae folium), drug-extract ratio 1:4 – 6, extraction solvent ethanol (70% V/V)

The other ingredients are: Liquid extract from peppermint leaves (Menthae piperitae folium), drug-extract ratio 1:4 – 6, extraction solvent ethanol (70% V/V), L-menthol, sodium saccharin (E 954), hydroxypropyl cellulose, ethanol, purified water.

Alcohol content: approx. 68% (V/V)

1 puff = 126 mg = 0.14 ml.

What Bronchostop direct oromucosal spray looks like and contents of the pack:

BRONCHOSTOP direct oromucosal spray is a clear brown solution (spray for application in the oral cavity) with a characteristic odour and taste (especially of peppermint). The spray is available in brown glass bottles containing 15 ml (sufficient for at least 100 applications), with a spray pump and extended spray arm.

Marketing Authorisation Holder and Manufacturer

Kwizda Pharma GmbH, 1160 Vienna, Austria.

Reg. Nr.:

This leaflet was last revised in October 2020.