

Package Leaflet: Information for Patients

BRONCHOSTOP Bronchitis Acute Oral Drops, Solution

Active substances: Thyme liquid extract, Primrose root tincture

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 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 notice any side effects, talk to your doctor or pharmacist. This also applies to side effects not listed in this leaflet. See section 4.
- If you do not feel better or feel worse after 7 days, talk to your doctor.

What is in this leaflet

1. What BRONCHOSTOP Bronchitis Acute is and what it is used for
2. What you need to know before you take BRONCHOSTOP Bronchitis Acute
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1. What BRONCHOSTOP Bronchitis Acute is and what it is used for

BRONCHOSTOP Bronchitis Acute is a herbal medicinal product for the treatment of productive cough associated with acute bronchitis in the context of a common cold.

This medicine is used in adults and children aged 6 years and older.

If you do not feel better or feel worse after 7 days, talk to your doctor.

2. What you need to know before you take BRONCHOSTOP Bronchitis Acute

Do not take BRONCHOSTOP Bronchitis Acute:

- if you are allergic (hypersensitive) to thyme, primrose root, any other member of the Lamiaceae (mint) family, 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 Bronchitis Acute.

If you develop fever, shortness of breath, or bloody sputum, consult a doctor immediately.

Caution is advised if you suffer from gastritis (inflammation of the stomach lining) or stomach ulcers.

Children under 6 years

Use in children under 6 years of age is not recommended due to insufficient data.

Taking BRONCHOSTOP Bronchitis Acute together with other medicines

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

No interactions have been reported to date.

No interaction studies have been conducted.

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.

Due to insufficient data, the use of this medicine during pregnancy and breast-feeding is not recommended.

Driving and using machines

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

BRONCHOSTOP Bronchitis Acute contains ethanol (alcohol) and preservatives

This medicine contains 262 mg of alcohol (ethanol) per 29 drops, or 308 mg of alcohol (ethanol) per 34 drops. The amount in 29 drops of this medicine is equivalent to less than 7 ml of beer or 3 ml of wine. The amount in 34 drops of this medicine is equivalent to less than 8 ml of beer or 4 ml of wine. The small amount of alcohol in this medicine will not have any noticeable effects.

BRONCHOSTOP Bronchitis Acute contains the preservatives methyl-4-hydroxybenzoate and propyl-4-hydroxybenzoate. These may cause allergic reactions, including delayed reactions.

3. How to take BRONCHOSTOP Bronchitis Acute

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 aged 12 years and older:

5 times daily, 34 drops

Total daily dose: 170 drops (equivalent to 2.1 g thyme liquid extract and 1.1 g primrose root tincture per day)

Children aged 6-11 years:

3 to 5 times daily, 29 drops

Total daily dose: up to 145 drops (equivalent to 1.8 g thyme liquid extract and 0.9 g primrose root tincture per day)

Children under 6 years:

Use in children under 6 years of age is not recommended due to insufficient data.

Method of administration:

For oral use.

Shake before use.

If possible, take BRONCHOSTOP Bronchitis Acute undiluted (e.g. applied onto sugar). You may also take BRONCHOSTOP Bronchitis Acute diluted (with a little water or warm tea).

Duration of use:

If you do not feel better or feel worse after 7 days, talk to your doctor.

If you take more BRONCHOSTOP Bronchitis Acute than you should

Poisoning with preparations of thyme and primrose root has not been reported to date.

In case of overdose, stomach discomfort, vomiting, or diarrhoea may occur. In such cases, contact a doctor who can decide on any necessary measures.

If you forget to take BRONCHOSTOP Bronchitis Acute

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 following frequency categories are used to evaluate side effects:

Very common: may affect more than 1 in 10 people

Common: may affect up to 1 in 10 people

Uncommon: may affect up to 1 in 100 people

Rare: may affect up to 1 in 1,000 people

Very rare: may affect up to 1 in 10,000 people

Not known: frequency cannot be estimated from the available data

Signs of a very rare possible allergic reaction include, but are not limited to, swelling of the face, mouth and/or throat, difficulty swallowing, shortness of breath, skin rash, or hives. If any of these symptoms occur, consult a doctor immediately, who will decide on further measures.

Very rarely, gastrointestinal complaints such as cramps, nausea, vomiting, and diarrhoea may occur.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This also applies to any side effects not listed in this leaflet.

You can also report side effects directly via the national reporting system:

Federal Office for Safety in Health Care

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 Bronchitis Acute

No special storage conditions are required for the unopened medicinal product. Use the contents within 12 weeks after opening. 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 carton or label after 'Use by'. The expiry date refers to the last day of that month.

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 Bronchitis Acute contains

- The active substances are:

1 ml (equivalent to 0.98 g or approximately 31 drops) contains:

392 mg liquid extract of thyme (Thymi herba), drug-extract ratio (DER) 1:2-2.5; extraction solvent: ammonia solution

10% (m/m) : glycerol 85% (m/m) : ethanol 90% (V/V) : water in the ratio 1 : 20 : 70 : 109.

196 mg tincture of primrose root (*Primulae radix*), drug-to-extraction-solvent ratio = 1:5, extraction solvent: ethanol 50% (V/V).

- The other ingredients are:

Purified water, ethanol 96%, glycerol 99.5%, betadex, sucralose, peppermint oil, methyl-4-hydroxybenzoate, propyl-4-hydroxybenzoate.

Total ethanol content: approx. 35% (V/V)

What BRONCHOSTOP Bronchitis Acute looks like and contents of the pack

BRONCHOSTOP Bronchitis Acute is a brownish liquid (oral drops, solution) with a characteristic thyme odour. Due to the herbal active substances, turbidity and flocculation may occur, which may lead to colour changes; however, these do not affect the quality of this medicine.

It is filled in amber glass bottles with an original sealed dropper and screw cap in 30 ml, 50 ml, and 100 ml. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Kwizda Pharma GmbH, 1160 Vienna

Authorisation number: 139032

This leaflet was last revised in June 2024.