

PACKAGE LEAFLET:
INFORMATION FOR THE USER



Bronchipret® Syrup TE

Liquid for oral use

Active substances:

Fluid extract of thyme herb

Fluid extract of ivy leaves

For use in children from one year of age and adults.

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to take Bronchipret Syrup TE carefully to get the best results from it.

Keep this leaflet. You may need to read it again.

Ask your pharmacist if you need more information or advice.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Bronchipret Syrup TE is and what it is used for
2. Before you take Bronchipret Syrup TE
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1. WHAT BRONCHIPRET SYRUP TE IS AND WHAT IT IS USED FOR

Herbal medicine for colds of the respiratory tract.

For the treatment of acute bronchitis with cough being a symptom of a cold, characterized by excessive mucous congestion.

2. BEFORE YOU TAKE BRONCHIPRET SYRUP TE

DO NOT take Bronchipret Syrup TE

If you are hypersensitive (allergic) to ivy, plants of the aralia family, thyme or other labiates (Lamiaceae), birch, mugwort, celery or to any of the other ingredients of Bronchipret Syrup TE listed under section 6.

Take special care with Bronchipret Syrup TE

For complaints lasting longer than one week, or if shortness of breath, fever or purulent or bloody expectoration occurs, a doctor should be contacted immediately.

Children

Bronchipret Syrup TE should not be used in children under one year of age.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking Bronchipret Syrup TE with food and drink

Not applicable.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Bronchipret Syrup TE should not be used during pregnancy and breast-feeding due to insufficient studies.

Driving and using machines

No special precautions are required.

Important information about some of the ingredients of Bronchipret Syrup TE

This medicine contains 7 vol.-% alcohol.

This medicine contains maltitol solution. Please do not take Bronchipret Syrup TE until after consulting your doctor if you know that you have an intolerance to certain sugars.

3. HOW TO TAKE BRONCHIPRET SYRUP TE

Always take Bronchipret Syrup TE exactly according to the instructions in this leaflet. You should check with your doctor or pharmacist if you are not sure.

If not prescribed otherwise by your doctor the usual dose is:

| Age | Single dose in ml (3 x daily) | Total daily dose |
|---|----------------------------------|------------------|
| Children from 1 to 5 years | 3.2 ml | 9.6 ml |
| Children from 6 to 11 years | 4.3 ml | 12.9 ml |
| Adults and adolescents from 12 years of age | 5.4 ml | 16.2 ml |

Method of administration

Using the enclosed measuring cup take Bronchipret Syrup TE three-times daily (in the morning, at midday and in the evening) undiluted or with some water. If needed some liquid (no alcohol), preferably a glass of water, can be drunk afterwards. Bronchipret Syrup TE can be taken together with food and drink or independent of meals. If you have a sensitive stomach you should take Bronchipret Syrup TE preferably after meals.

Shake before use!

Duration of the treatment

The duration of treatment depends on the course of the illness. If complaints persist longer than one week a doctor should be consulted immediately.

If you take more Bronchipret Syrup TE than you should

In case of overdose, gastric complaints, vomiting and maybe diarrhoea are possible. In this case, please notify your doctor. Your doctor can decide whether any other action is necessary.

If you forget to take Bronchipret Syrup TE

If you have taken too few Bronchipret Syrup TE or have forgotten to take Bronchipret Syrup TE, do not take a double dose the next time, but rather continue taking it as prescribed by your doctor or as described in this leaflet.

If you stop taking Bronchipret Syrup TE

Discontinuing Bronchipret Syrup TE is usually harmless. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Bronchipret Syrup TE can cause side effects, although not everybody gets them.

With regard to the frequency of side effects the following categories are used:

Very common:

more than 1 out of 10 persons treated

Common:

1 to 10 out of 100 persons treated

Uncommon:

1 to 10 out of 1,000 persons treated

Rare:

1 to 10 out of 10,000 persons treated

Very rare:

less than 1 out of 10,000 persons treated

Not known:

frequency cannot be estimated from the available data

Significant side effects or signs to which you should pay attention, and actions to take if you are affected

If you are affected by one of the following side effects, do not take any more Bronchipret Syrup TE and contact your doctor as quickly as possible. The doctor can determine the severity and whether any further action is necessary.

Uncommonly, gastrointestinal complaints such as cramps, nausea and vomiting may occur.

Rarely, hypersensitivity reactions (allergic reactions) with skin rashes may occur. Hypersensitivity reactions, including shortness of breath, urticaria and swelling of the face, mouth and/or throat may also occur. At the first sign of a hypersensitivity reaction, Bronchipret Syrup TE must not be taken again.

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 Bundesinstitut für Arzneimittel und Medizinprodukte [Federal Institute for Drugs and Medical Devices], Abt. Pharmakovigilanz [dept. Pharmacovigilance], Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, website: www.bfarm.de. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE BRONCHIPRET SYRUP TE

Keep this medicine out of the sight and reach of children.

Do not use Bronchipret Syrup TE after the expiry date which is stated on the carton and the bottle. The expiry date refers to the last day of that month.

Storage conditions

Do not store above 25 °C.

Store this medicine in its original container to protect the contents from light.

Information on shelf life after opening

May be kept for 6 months after opening.

6. FURTHER INFORMATION

What Bronchipret Syrup TE contains:

The active substances are:

100 ml (correspond to 112 g) liquid for oral use contain:
16.8 g fluid extract of thyme herb (1:2-2.5); extracting agent: 10% ammonia solution (m/m); 85% glycerol (m/m); 90% ethanol (v/v); water (1:20:70:109); 1.68 g fluid extract of ivy leaves (1:1); extracting agent: 70% ethanol (v/v)
This medicine contains 7 vol.-% alcohol.

The other ingredients are:

Citric acid monohydrate, purified water, hydroxypropylbetadex, potassium sorbate, maltitol solution

Information for diabetics:

A single dose of Bronchipret Syrup TE (5.4 ml) contains an average of 0.18 carbohydrate exchange units (CEU).

What Bronchipret Syrup TE looks like and contents of the package

Bronchipret Syrup TE is available in packages containing 50 ml (N1) and 100 ml (N2). Bronchipret Syrup TE is a light brown, clear liquid.

Marketing Authorisation Holder and Manufacturer

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