

Package leaflet:
Information for the user



Bronchipret® TP

Film-coated tablets

Active substances: dry extract of primula root
dry extract of thyme herb
For use in adolescents from the age of 12 years and in 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 use Bronchipret TP 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 TP is and what it is used for
2. Before you take Bronchipret TP
3. How to take Bronchipret TP
4. Possible side effects
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1. WHAT BRONCHIPRET TP IS AND WHAT IT IS USED FOR

Bronchipret TP is an herbal medicine for the treatment of colds affecting the respiratory tract.

For treatment of the symptoms of acute bronchitis with a cough and colds characterized by a thick mucus.

2. BEFORE YOU TAKE BRONCHIPRET TP

DO NOT take Bronchipret TP:

If you are hypersensitive (allergic) to the active substances or to other labiates (Lamiaceae), birch, mugwort, celery or to any of the other ingredients in this medicinal product listed in Section 6.

Warnings and precautions:

Please talk to your doctor or pharmacist before you take Bronchipret TP. If complaints last longer than two weeks or if breathing difficulties, fever or purulent or bloody sputum occur, contact a doctor immediately. Special care must be taken in patients with gastritis or ulcers.

Use in children:

Bronchipret TP should not be used in children under 12 years of age. There are insufficient data on its use in children under 12 years of age.

Taking other medicines:

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

There are no known interactions with other medicines to date. There are no data on potential interactions between Bronchipret TP and other medicines that are taken simultaneously.

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.

Bronchipret TP should not be used during pregnancy and breast-feeding due to the lack of relevant data. There are no data on the effects on fertility/parity in humans. No adverse effects were observed on fertility/parity in animal experiments.

Driving and using machines:

No special precautions are required.

Bronchipret TP contains glucose and lactose.

Please only take Bronchipret TP after consulting your doctor if you know that you have an intolerance to certain sugars.

3. HOW TO TAKE BRONCHIPRET TP

Always take Bronchipret TP exactly as instructed in this package leaflet. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Adolescents from the age of 12 years and adults take 1 film-coated tablet 3 times daily.

Method of administration:

Take Bronchipret TP unchewed before meals with sufficient liquid (preferably a glass of water).

Duration of administration:

The duration of the treatment depends on the course of the disease. If complaints last longer than two weeks, please consult your doctor as soon as possible.

If you take more Bronchipret TP than you should:

In cases of an overdose, stomach complaints, vomiting and possibly diarrhoea may occur. In this case, please inform a doctor. The doctor will then decide on any necessary measures.

If you forget to take Bronchipret TP:

Do not take a double dose if you have forgotten to take the previous dose.

If you stop taking Bronchipret TP:

It is usually safe to stop taking the medicine.

If you have any further questions on the use of this product, 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 possible side effects is based on the following categories:

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:

fewer than 1 out of 10,000 persons treated

Unknown:

frequency cannot be estimated from the available data

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

If you are affected by any of the side effects listed below, you should stop taking Bronchipret TP and consult your doctor as soon as possible. The doctor will decide on the severity of the side effect and on any necessary further measures.

Gastrointestinal complaints, such as cramps, nausea, vomiting and diarrhoea, are **uncommon**.

In **very rare** cases, hypersensitivity reactions (allergic reactions), such as shortness of breath, urticaria or swelling of the face, mouth and/or throat may occur. Stop taking Bronchipret TP at the first signs of a hypersensitivity reaction.

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 TP

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

Do not use Bronchipret TP after the expiry date which is stated on the carton or container (blister pack). The expiry date refers to the last day of that month.

Storage conditions:

Do not store above 25°C.

6. FURTHER INFORMATION

What Bronchipret TP contains:

The active substances are:

1 Bronchipret TP film-coated tablet contains:

60 mg dry extract of primula root (6-7:1)

extraction solvent: ethanol 47.4 % (V/V),

160 mg dry extract of thyme herb (6-10:1)

extraction solvent: ethanol 70 % (V/V).

The other ingredients are:

Chlorophyllin a - copper complex trisodium salt (E141), crospovidone, dimeticone, glucose-syrup, colloidal silicon dioxide, hypromellose, lactosemonohydrate, magnesium stearate, microcrystalline cellulose, peppermint flavouring, polyacrylate dispersion 30%, povidone K25, propylene glycol, riboflavin (E 101), saccharin sodium, talc, titanium dioxide (E 171).

Note for diabetics:

1 Bronchipret TP film-coated tablet contains an average of 0.02 calculable carbohydrate exchange units (CEU).

Bronchipret TP is gluten-free.

What Bronchipret TP looks like and contents of the pack:

Packs of 20 (N1) film-coated tablets, 1 blister strip with 20 film-coated tablets

Packs of 50 (N2) film-coated tablets, 2 blister strips with 25 film-coated tablets each

Packs of 100 (N3) film-coated tablets, 4 blister strips with 25 film-coated tablets each

Bronchipret TP are green, round, biconvex film-coated tablets with a semimatt surface.

Marketing Authorization Holder and Manufacturer:

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