Package leaflet: Information for the user



Bronchipret® Thyme Lozenges

42.0 mg / lozenge

Active substance: dry extract of thyme herb For use in children older than 6 years 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 Thyme Lozenges as directed to get the best results from it.

- Keep this package leaflet. You may need to read it again.
- Askyour doctor or pharmacist if you need more information or advice.
 You must contact a doctor if your symptoms worsen or do not
- improve after 1 week.
- 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 Thyme Lozenges are and what they are used for
- 2. Before you take Bronchipret Thyme Lozenges
- 3. How to take Bronchipret Thyme Lozenges
- 4. Possible side effects
- 5. How to store Bronchipret Thyme Lozenges
- 6. Further information

WHAT BRONCHIPRET THYME LOZENGES ARE AND WHAT THEY ARE USED FOR

Herbal medicinal product for the treatment of respiratory cold diseases

Relieves respiratory cold symptoms with viscous mucus and bronchial complaints.

2. BEFORE YOU TAKE BRONCHIPRET THYME LOZENGES

Do NOT take Bronchipret Thyme Lozenges:

In case of hypersensitivity (allergy) to thyme or other Lamiaceae (Labiatae), birch, mugwort, celery or any of the other excipients (see also section 6 FURTHER INFORMATION)

Take special care with Bronchipret Thyme Lozenges:

Contact a doctor immediately if complaints persist for more than one week or if symptoms such as dyspnea, fever as well as purulent or bloody sputum are observed.

Children:

There are no sufficient data available on the use of Bronchipret Thyme Lozenges in children younger than 6 years. Bronchipret Thyme Lozenges should therefore not be given to children younger than 6 years.

Seniors:

There are no known restrictions for older people.

Taking other medicines:

There are no data available for possible interactions with other medicines.

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

Taking Bronchipret Thyme Lozenges with food and drink:

There are no known interactions between Bronchipret Thyme Lozenges and natural stimulants, food or drinks.

Pregnancy and breast-feeding:

Wide-spréad consumption of thyme in food products has provided no evidence that there are any risks for pregnant and breast-feeding women.

However, there are no sufficient data available on the use of Bronchipret Thyme Lozenges in pregnant and breast-feeding women. The use of Bronchipret Thyme Lozenges is therefore not recommended for pregnant and breast-feeding women.

Ask your doctor or pharmacist before taking any medicine.

Driving and using machines:

No special precautions necessary for medicines that contain thyme.

Important information about some of the ingredients of Bronchipret Thyme Lozenges:

One lozenge of this medicine contains 0.376 g maltitol and 0.009 g glucose syrup. Ask your doctor for advice if you have a known intolerance to certain sugars.

3. HOW TO TAKE BRONCHIPRET THYME LOZENGES

Always take Bronchipret Thyme Lozenges exactly as directed in this package leaflet. You should check with your doctor or pharmacist if you are not sure.

Unless prescribed otherwise by your doctor, the usual dose is: Adults and adolescents older than 12 years take 3-4 lozenges 3-4 times daily.

Children between 6-11 years take 2-3 lozenges 4 times daily.

Medthod of administration:

Suck lozenges (do not chew) so that the active substances can already be taken up in the throat.

Duration of administration:

The length of time during which you can take Bronchipret Thyme Lozenges ist not limited. See also sections "Take special care with Bronchipret Thyme Lozenges" and "Possible side effects"

Ask your doctor or pharmacist if you have the impression that the effects of Bronchipret Thyme Lozenges are too strong or too weak.

If you take more Bronchipret Thyme Lozenges than you should:

Generally, there are no negative consequences if you took by mistake one or two single doses more than directed. If you took significantly greater amounts you should inform your doctor. Your doctor will decide if any action needs to be taken. Possible side effects may be more pronounced.

If you forget to take Bronchipret Thyme Lozenges:

If you took a smaller dose of Bronchipret Thyme Lozenges as directed or if you forgot to take Bronchipret Thyme Lozenges do not take a double dose to make up for it but continue taking Bronchipret Thyme Lozenges as prescribed by your doctor or as directed in the package leaflet.

If you stop taking Bronchipret Thyme Lozenges:

In general, no special precautions are required when discontinuing Bronchipret Thyme Lozenges.

If you have further questions on the use of this product ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Bronchipret Thyme Lozenges can cause side effects, although not everybody gets them.

The evaluation of possible side effects is based on the following frequency rates:

Verv 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

Unknown:

Frequency cannot be estimated from the available data

Hypersensitivity reactions and/or allergic reactions of the skin and the respiratory system such as dyspnea, skin rash, urticaria and swellings in the face, mouth and/or pharynx (Quincke's edema) may occur.

Additionally, stomach and bowel symptoms such as cramps, nausea and 0.045 carbohydrate exchange units (CEU). vomiting may occur.

The frequency of these side effects is unknown.

If you observe any of the listed side effects especially swellings in the face, mouth or pharynx or any allergic reactions of the respiratory system, discontinue taking Bronchipret Thyme Lozenges and contact a doctor immediately. Your doctor will decide on the severity of the side effects and if any action needs to be taken.

At the first signs of a hypersensitivity reaction Bronchipret Thyme Lozenges 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 THYME LOZENGES

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the container and the blisters. The expiry date refers to the last day of that month.

Storage conditions:

For this medicine there are no special storage conditions required.

6. FURTHER INFORMATION

What Bronchipret Thyme Lozenges contain:

The active substance is:

1 lozenge contains: 42.0 mg dry extract of thyme herb (6-10 : 1); extracting agent: ethanol 70 % (V/V).

The other ingredients are:

Gum arabic, Betadex, highly-fluid paraffin, black current flavour, wild berry flavour, bleached wax, glucose syrup, maltitol solution, sodium cyclamate, saccharine sodium, highly disperse silicon dioxide.

Note for diabetics:

One Bronchipret Thyme Lozenge contains approximately 0.045 carbohydrate exchange units (CEU).

What Bronchipret Thyme Lozenges look like and contents of the pack:

Packages with 20 (sample not for sale), 30 and 50 (N2) lozenges. Not all package sizes may be marketed.

Marketing Authorization Holder and Manufacturer

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