Package Information Leaflet: Information for the User



# **Bronchipret® Drops**

Liquid for oral use

Active substances: Thyme herb - fluid extract Ivy leaves - fluid extract For use in children of 6 years of age and up and adults

Please read the entire package leaflet carefully because it contains important information for you.

#### This medicine is available without a prescription. In order to achieve the best treatment results, Bronchipret Drops must nevertheless be taken as prescribed.

- Keep this leaflet. You may need to read it again.
- Ask your doctor or pharmacist if you need further information or advice.
- If your symptoms worsen or do not improve after one week, you must consult a doctor.
- If any of the side effects gets serious, or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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# 1. What are Bronchipret Drops and what they are used for?

Bronchipret Drops are a herbal medicine for the treatment of colds in the airways.

For improving the symptoms of acute inflammatory bronchial diseases and acute inflammation of the airways with the accompanying symptom of a "cough with viscous mucus".

2. What you need to know before you take Bronchipret Drops.

# Bronchipret Drops must not be taken:

If you are hypersensitive (allergic) to ivy, thyme or other members of the mint family (Lamiaceae), birch, mugwort, celery or any of the other ingredients of Bronchipret Drops (for the other ingredients see section 6 Further Information).

# Special care is required when taking Bronchipret Drops:

In the case of symptoms which last for longer than one week, or if you have difficulty breathing or a fever or cough up matter containing pus or blood, a doctor should be consulted immediately.

# Children:

Bronchipret Drops should not be given to children under the age of 6 years. Insufficient studies have been carried out on the use of this product in children under 6 years of age.

# Taking Bronchipret Drops with other medicines:

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

There are no known interactions with other medicines.

No studies have been carried out on Bronchipret Drops and any possible interactions with other medicines administered at the same time.

# Pregnancy and breast-feeding:

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

Bronchipret Drops should not be taken if you are pregnant or breast-feeding as insufficient studies have been carried out.

# Ability to drive and use machines:

No particular precautionary measures are required.

# Important information about some of the other ingredients of Bronchipret Drops:

This medicinal product contains 24% alcohol by volume.

3. How to take Bronchipret Drops.

Always take Bronchipret Drops exactly as described in this leaflet. Please check with your doctor or pharmacist if you are not sure.

Unless otherwise prescribed by your doctor, the usual dose is:

Age	Single dose in ml (3 times a day)	Total daily dose
Adolescents aged 12 years and up and adults	2.6 ml	7.8 ml
Children from the age of 6 to 11 years	1.3 ml	3.9 ml

# Method of administration:

Use the enclosed measuring cup to dose this medication and take Bronchipret Drops 3 times a day (in the morning, at lunchtime and in the evening), if necessary with a little fluid (e. g. a glass of water).

Slight cloudiness or flocculation may occur during storage, but does not affect the effectiveness of this product.

Shake well before each use!

# Length of administration:

The length of the treatment depends on the course of the disease. Please always note the information in the first paragraph under "Special care is required when taking Bronchipret Drops" as well as the information under "Side effects".

Please talk to your doctor or pharmacist if you have the impression that the effect of Bronchipret Drops is too strong or too weak.

#### If you have taken more Bronchipret Drops than you should:

An overdose may cause stomach discomfort, vomiting and possibly diarrhoea. Please notify a doctor in this case. He or she can decide on any necessary further measures.

# If you forget to take Bronchipret Drops:

If you have taken too little Bronchipret Drops or forgot to take a dose, do not take twice as much the next time you take it, but continue as prescribed by your doctor or as described in the dosage instructions.

# If you stop taking Bronchipret Drops:

If you stop taking Bronchipret Drops, this is usually harmless. If you have any further questions on the use of this medicine, please consult your doctor or pharmacist.

# 4. Possible side effects

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

Any assessment of side effects is based on the following specifications of frequency:

#### Very common:

occurs in more than 1 in 10 patients Common: occurs in more than 1 in 100 patients Uncommon: occurs in 1 to 10 patients in 1,000 Rare: occurs in 1 to 10 patients in 10,000 Very rare: occurs in fewer than 1 patient in 10,000 Unknown: Frequency cannot be estimated on the basis of the data available.

# Significant side effects or symptoms you should look out for, as well as measures if you are affected:

If you are affected by any of the following side effects, stop taking Bronchipret Drops and consult your doctor as soon as possible. He or she can then decide on their severity and any necessary further measures.

Occasionally, gastrointestinal problems such as cramps, nausea or vomiting may occur.

Very rarely, hypersensitivity reactions (allergic reactions) such as shortness of breath, skin rashes, nettle rash and swelling of the face, mouth and/ or throat can occur. At the first signs of a hypersensitivity reaction, Bronchipret Drops 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 to the Federal Institute for Drugs and Medical Devices (BfArM), Pharmacovigilance Department, Kurt-Georg-Kiesinger-Allee 3, 53175 Bonn, Germany, 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 Drops.

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 the outer carton. The expiry date refers to the last day of that month.

# Storage conditions:

This pharmaceutical product does not require any special storage conditions. Shelf life after opening: 6 months.

# 6. Further information

# What Bronchipret Drops contain:

The active substances are: 1 ml (corresponding to 1 g) of liquid for oral use: Pharmaceutically active substances: 0.5 ml fluid extract from thyme herb (1:2 - 2.5 ml), extracting agent: ammonia solution 10% (m/m) : glycerol 85% (m/m) ethanol 90% (V/V) : water (1:20:70:109) 0.03 ml fluid extract from ivy leaves DAC (1:1), extracting agent: ethanol 70% (V/V).

Contains 24% alcohol by volume.

# The other ingredients are:

Citric acid monohydrate, ethanol 96% (V/V), purified water, hydroxyprophylbetadex (MS: 0.65), saccharin-sodium dihydrate.

# Information for diabetics:

A single dose of Bronchipret Drops does not contain any relevant numbers of bread units (BU).

Bronchipret Drops are gluten-free.

#### What Bronchipret Drops looks like and contents of the pack: Packs containing 50 ml (N2) and 100 ml (N3) liquid for oral use.

Bronchipret Drops is a brownish clear liquid.

# Marketing Authorisation Holder and Manufacturer:

# **BIONORICA SE**

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