

**Bronchicum® Elixir S**

sanofi aventis

*Liquid extract from thyme and from primula root***For administration in infants from 6 months of age, in children, adolescents and adults.**

Read all of this leaflet carefully before you start using this medicine, because it contains important information for you. Bronchicum® Elixir S may be obtained in pharmacies without prescription. However, to obtain an optimum therapeutic success, it should be taken according to instructions.

- Keep this leaflet, maybe you need to read it again.
- If you have any further questions, please ask your pharmacist.
- If your symptoms aggravate or if there is no improvement after some days, please consult your doctor.
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

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**1) WHAT BRONCHICUM® ELIXIR S IS AND WHAT IT IS USED FOR**

Bronchicum® Elixir S is a herbal medicinal preparation used in colds of the respiratory tract.

Bronchicum® Elixir S is used for the treatment of symptoms of acute bronchitis and in colds of the respiratory tract with mucous secretion.

**2) BEFORE YOU USE BRONCHICUM® ELIXIR S**

Do not use Bronchicum® Elixir S.

• If you are allergic to primula, thyme or other lamiceae (labiate plants) or to any other ingredient.

**Take special care with Bronchicum® Elixir S**

Consult immediately your doctor if the complaints are persisting or in the event of dyspnea, fever above 39°C, purulent or bloody sputum.

**Children**

The use of Bronchicum® Elixir S in infants younger than 6 months of age has not been adequately studied. This syrup must therefore not be given to infants younger than 6 months of age.

**Taking other medicines**

No interactions are known.

Please inform your doctor or pharmacist if you are taking or have recently taken other medicines, even those not prescribed.

**Pregnancy and breast-feeding**

The wide use of thyme as medicine or as food has not yielded any signs that would involve a risk for pregnancy and breast-feeding. Specific results from investigations into thyme and primula root during pregnancy and breast-feeding are not available. Therefore, the use of Bronchicum® Elixir S in pregnant or breast-feeding women is not recommended.

**Driving and using machines**

No special precautions.

**Further information about Bronchicum® Elixir S**

Bronchicum® Elixir S contains 4.9% vol. ethanol.

It contains sucrose and invert sugar. Please consult your doctor when you know about any intolerance of specific sugars before taking Bronchicum Elixir S

**3) HOW TO USE BRONCHICUM ELIXIR S**

Always take Bronchicum® Elixir S exactly as instructed in this leaflet.

If you have any uncertainty you must discuss this with your doctor or pharmacist.

Unless otherwise prescribed by the doctor, the usual posology is:

Age (body weight)	Single dose	Daily dose
Infants of 6-12 months (about 6-10 kg)	1.0 ml 6 times daily	6.0 ml
Toddlers, young children from 1-4 years (about 8-16 kg)	2.5 ml 6 times daily	15 ml
Children from 5 years, adolescents and adults	7.5 ml 4 times daily	30 ml

Take Bronchicum® Elixir S distributed over the day at regular intervals. Maybe hit the bottom of the bottle to facilitate pouring out.

The duration of the application is not limited. However, consider the information given in sections 2 and 4 (side effects) of this leaflet.

Tell your doctor or pharmacist if you have the impression that the effect of Bronchicum® Elixir S is too strong or too weak.

**If you use more Bronchicum® Elixir S than you should**

The side effects listed below may be more pronounced. Consult your doctor if this is the case. He or she may decide about any measures to be taken.

**If you forget to take Bronchicum® Elixir S**

In case you have not taken enough Bronchicum® Elixir S or forgotten an application take the dose as soon as possible, then continue as instructed. However, if you have forgotten to take Bronchicum® Elixir S a whole day, do not take the missing dose, but continue as usual the next day.

Ask your doctor or pharmacist for any further questions about the use.

**4) POSSIBLE SIDE EFFECTS**

Like all medicines, Bronchicum® Elixir S can have side effects.

For the evaluation of adverse effects the following classification is considered:

Very common:	occurring in more than 1 of 10 people who use this medication
Common:	occurring in 1 to 10 of 100 people who use this medication
Uncommon:	occurring in 1 to 10 of 1,000 people who use this medication
Rare:	occurring in 1 to 10 of 10,000 people who use this medication
Very rare:	occurring in less than 1 of 10,000 people who use this medication
Not known:	incidence cannot be assessed on grounds of the data available

**Significant side effects and symptoms you may notice and any measures**

Hypersensitivity reactions may occur, such as cutaneous rash or nettle rash (exanthema, urticaria) as well as swellings in the face, the mouth and/or the throat (Quincke's edema) associated with shortness of breath (dyspnea). On very rare occasions also gastro-intestinal complaints may occur, such as nausea, vomiting and diarrhea, and very rarely convulsions.

In infants under 12 months of age vomiting may occur commonly.

**Note**

In case you notice any of the mentioned side effects, especially swellings in the face, the mouth and/or the throat, stop using Bronchicum® Elixir S and tell immediately your doctor who will decide about the severity and take any measures that might be necessary.

Stop taking Bronchicum® Elixir S when you notice any sign of hypersensitivity.

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

**5) STORING Bronchicum® Elixir S**

Keep out of the reach of children!

The expiry date of this package is stated on the label and on the folding carton.

The expiry date refers to the last day of that month. Do not use after this date.

**Storage conditions**

**Do not store above 25°C.**

**Shelf life after opening**

Once the bottle has been opened, Bronchicum® Elixir S may be used for 6 months below 25°C.

**6) FURTHER INFORMATION**

**Ingredients of Bronchicum® Elixir S**

100 g of the liquid (equiv. to 75.36 ml) contain as active ingredients :

5.0 g of thyme liquidextract (1 : 2-2.5)

extraction solvent: ammonia solution 10% (m/m), glycerol 85%, ethanol 90% (V/V), water = 1:20:70:109

And 2.5 g of Primula root liquid extract (1 : 2-2.5)

extraction solvent: ethanol 70% (m/m)

Other ingredients: mixture of sucrose and invert sucrose, sodium benzoate, purified water.

**Information for diabetics**

5 ml correspond to 0.38 BU (white bread units). Caloric value: 77kJ = approx. 18 kcal per 5 ml.

**Presentation of Bronchicum® Elixir S**

Bottle of 100ml.

Bronchicum® Elixir S contains extracts of plant origin; occasionally sedimentations or flocculations may appear which do not affect the efficacy of the preparation.

**Manufacturer**

A. Nattermann & Cie. GmbH,

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For sanofi-aventis

This leaflet was last revised: September 2009