

## **Package leaflet: Information for the user**

### **Broncophen Sine, syrup**

Thyme herb dry extract / Marshmallow root liquid extract

#### **Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after five days.

#### **What is in this leaflet:**

1. What Broncophen Sine is and what it is used for
2. What you need to know before you take Broncophen Sine
3. How to take Broncophen Sine
4. Possible side effects
5. How to store Broncophen Sine
6. Contents of the pack and other information

#### **1. What Broncophen Sine is and what it is used for**

Broncophen Sine is a traditional herbal medicinal product with an indication based upon long-standing use.

Relieves throat irritation and promotes expectoration of mucus in cough associated with upper respiratory tract virus infections.

#### **2. What you need to know before you take Broncophen Sine**

##### **Do not take Broncophen Sine**

If you are allergic to active substance(s), other members of the *Lamiaceae* family or any of the other ingredients of this medicine (listed in section 6).

##### **Warnings or precautions**

In case of fever, shortness of breath and/or purulent discharge, a doctor should be consulted

##### **Children**

This medicine is not recommended for use in children aged up to 2 years due to lack of data and because of the medical advice can be necessary.

##### **Other medicines and Broncophen Sine**

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

No interactions with other medicinal products are known.

**Broncophen Sine with food and drink**

There is no available data investigating the effect of food or drink on the medicine's action.

**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.

In the absence of sufficient data, the use during pregnancy and breast-feeding is not recommended.

**Driving and using machines**

No investigations on the effects on the ability to drive and use machines have been performed.

**Broncophen Sine contains methyl-parahydroxybenzoate and propyl-parahydroxybenzoate**

These may cause allergic reactions which may also appear as a delayed reaction (see "Do not take Broncophen Sine").

**Broncophen Sine contains xylitol.**

Xylitol may have a laxative effect. Calorific value 2.4 kcal/g xylitol.

**Broncophen Sine contains raspberry juice concentrate which contains sucrose, glucose and fructose.**

This medicine contains 131 mg sugars in 15 ml of syrup.

If your doctor has told you that you or your child have an intolerance to some sugars, talk to your doctor before you (or your child) take or receive this medicine.

**Broncophen Sine contains propylene glycol.**

This medicine contains 33.3 mg of propylene glycol in 15 ml of syrup.

**3. How to take Broncophen Sine**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

**The recommend dose is:**Adults and adolescents over 12 years of age:

15 ml every 3-4 hours, 4-6 times per day, with maximum daily dosage up to 90 ml.

Children between 4–12 years of age:

7.5 ml every 3-4 hours, 4-6 times per day, with maximum daily dosage up to 45 ml.

Children between 2–4 years of age:

After consulting a doctor, 7.5 ml may be administered every 3-4 hours, 4-6 times per day, with maximum daily dosage up to 45 ml.

Children up to 2 years:

This medicine is not recommended for use in children aged up to 2 years due to lack of data and because of no advice can be given for use of medicine.

*Method of administration:*

Oral use.

Take Broncophen Sine undiluted, using enclosed measuring cup with scale marks between 2.5 ml and 20 ml.

If required, Broncophen Sine may be administered diluted in water or warm tea.

*Duration of administration:*

Treatment with Broncophen Sine should be limited to 5 days. Provided that no significant improvement has occurred by then, you are advised to consult a doctor, as your disease may be more serious.

**If you take more Broncophen Sine than you should**

If you have taken a considerable overdose of this medicinal product, symptoms of known undesirable effects may occur more intensively. In this case, please inform your doctor. If necessary, he/she can make a decision on any measures required.

**If you forget to take Broncophen Sine**

Do not take a double dose to make up for a forgotten dose.

**If you stop taking Broncophen Sine**

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

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Hypersensitivity reactions as well as gastrointestinal disorders have been observed in connection with medicinal products containing thyme. Their frequency is not known.

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [www.ravimiamet.ee](http://www.ravimiamet.ee). By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. How to store Broncophen Sine**

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

Do not store above 25°C.

Store the bottle in the original package in order to protect from light.

Do not use this medicine after the expiry date which is stated on the carton after “Use by”. The expiry date refers to the last day of that month.

Close the bottle firmly after use. After first opening the bottle, use the contents within 4 weeks.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## **6. Contents of the pack and other information**

### **What Broncophen Sine contains**

- The active substances are:

15 ml syrup contains:

120 mg thyme herb dry extract (7-13:1)

Extraction agent: water

830 mg marshmallow root liquid extract (1:13)

Extraction agent: water

- The excipients are:

Xylitol (E967), Methyl-parahydroxybenzoate (E218), Propyl-parahydroxybenzoate (E216), Raspberry juice concentrate (containing sucrose, glucose and fructose), Raspberry aroma flavour (synthetic and natural flavourings, propylene glycol (E1520)), Xanthan gum, Citric acid monohydrate (E330), Maltodextrin, Gum arabic, Purified water.

### **What Broncophen Sine looks like and contents of the pack**

Broncophen Sine is a brown-red, viscous solution for oral use with the scent and taste of thyme and raspberries.

The syrup is filled into 120 ml amber yellow glass bottles with plastic screw cap fitted with protective ring. Bottles are individually packaged in cardboard boxes with enclosed measuring cups, which have a marked scale between 2.5 ml and 20 ml. It facilitates precise measuring of recommended amounts.

In medicinal preparations like Broncophen Sine, which contain natural substances, the solution can become flaky or precipitate, as well as the preparation may accumulate or sediment to the inner surface of screw cap. This will not affect nor quality or effect of the preparation.

### **Marketing authorisation holder and manufacturer**

Kwizda Pharma GmbH  
Effingergasse 21,  
1160 Vienna  
Austria

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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**This information for the user was last revised in March 2019**