



Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

Bronchicum

2. PHARMACEUTICAL FORM

Elixir for Oral use.

3. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance: Thyme liquid extract, Primula root liquid extract.

Each 5ml of liquid contains:

Thyme fluid extract of the stripped and dried leaves and blossoms of thyme 0.325 gm

Ratio Drug: fluid extract = (1: 2.0-2.5) (m/m) extractant: {Purified water (109 parts), Ethanol 90% V/V (70 parts), Glycerol 85% (20 parts) & Ammonia solution 10% m/m (1 part)} (Phenolic Compound calculated as Thymol % = Not less than 0.03%)

Primula root fluid extracts 0.162 gm

Ratio Drug: fluid extract = (1: 2.0-2.5) (m/m) extractant: Ethanol 70% (m/m) (Primulic Acid = Not less than 0.2%)

For a full list of excipients, see Section 6.1.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications:

Bronchicum Elixir is a herbal medicine recommended in the treatment of respiratory infections following exposure to cold. Bronchicum Elixir is used to treat symptoms of acute bronchitis and respiratory infections with thick phlegm following exposure to cold.

4.2 Posology and method of administration

Posology

Age or (body weight)	Single dose	Total daily dose
Children over 6 years, adolescents and adults	7.5 ml 4 times a day	30 ml

Method of administration

Bronchicum Elixir should be taken in divided doses spread evenly throughout the day

There is no restriction on the duration of use. The patient's attention is drawn to the following in the information leaflet: "...you should seek medical advice if symptoms last more than 1 week. In any event you must take note of the information in the *warnings* and *undesirable effects* sections".

Bronchicum Elixir contains herbal extracts; occasional formation of flakes or deposits has no effect on efficacy.

This product contains Ethanol, So not to be used for more than one week and period between doses must not be less than 4 hours

4.3 Contraindications

This medicinal product must not be used in patients with known hypersensitivity to primrose, thyme or other plants of the Lamiaceae (Labiatae) family, or to any of the excipients listed in Section 6.1.

4.4 Special warnings and precautions for use

Bronchicum Elixir contains 4.9% (V/V) alcohol.

Patients with rare hereditary fructose intolerance, glucose galactose malabsorption or congenital sucrase-isomaltase deficiency should not take Bronchicum Elixir.

Children

Insufficient data are available concerning administration in children under 6 Years of age. Bronchicum Elixir should therefore not be given to children who are under 6 Years old due to presence of Alcohol



The patient's attention is drawn to the following in the information leaflet:

"If you experience difficulty breathing, fever over 39° C or phlegm containing pus or blood, you must go and see your doctor immediately."

4.5 Interaction with other medicinal products and other forms of interaction

There are no known interactions.

The patient's attention is drawn to the following in the information leaflet:

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

4.6 Fertility, pregnancy and lactation

Pregnancy and lactation:

The widespread use of thyme in medicines and foods, and the use of primula root as a medicine has not demonstrated any risks during pregnancy or breast-feeding to date. However, as the use of thyme and primrose preparations in pregnancy or breast-feeding has not been adequately studied, Bronchicum Elixir is not recommended for pregnant or breast-feeding women.

Fertility:

There are no studies available concerning the effect on fertility.

4.7 Effects on the ability to drive and use machines

Bronchicum Elixir has no effect on the ability to drive and operate machines.

4.8 Undesirable effects.

Hypersensitivity reactions such as exanthema, urticaria and angioedema may occur associated with dyspnea. Gastrointestinal effects, such as cramps, nausea, vomiting and diarrhea have also been observed. No information is available on the frequency of these possible side effects.

The patient's attention is drawn to the following in the information leaflet:

"If you experience any of the side effects mentioned above, particularly swelling of the face, mouth, and/or throat, stop taking Bronchicum Elixir and see a doctor immediately so that he or she can determine the severity of the effect and decide whether any measures are required.

At the first signs of a hypersensitivity reaction, stop taking Bronchicum Elixir".

Reporting of suspected undesirable effects Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via pharmacovigilance.eg@sanofi.com

4.9 Overdose

The patient's attention is drawn to the following in the information leaflet:

"If you take more Bronchicum Elixir than you should, the side effects mentioned below may be more severe. In this case, inform a doctor. He or she will decide whether any measures need to be taken.

If you have not taken enough Bronchicum Elixir or if you forget to take a dose, take it as soon as possible and then continue with the recommended or prescribed dose. However, if you forget to take Bronchicum Elixir for a whole day, do not take the doses you missed; instead, continue treatment on the following day as indicated in the package leaflet or as prescribed by your doctor".

If you drink the complete contents of the 100 ml bottle, you will have consumed approx. 3.9 g g of alcohol.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: R05CP51

There are scientific data available regarding the efficacy and safety of thyme liquid extract and primula root liquid extract. Results of *in vitro* and animal experiments with preparations of *Thymi herba* and thyme oil, as well as its main constituent thymol, show weak expectorant and spasmolytic actions. Antimicrobial actions have been demonstrated *in vitro* against a broad spectrum of gram-positive and gram-negative bacteria, yeasts and fungi. The expectorant effect probably results from activation of ciliary motility in the bronchial epithelium caused by reflexive stimulation of the vagus nerve via the



gastric mucosa, as well as direct stimulation of the sero-mucous glands as a result of pulmonary secretion after successful absorption.

Primula root preparations develop their expectorant action predominantly by local stimulation of the gastric mucosa by poorly absorbed saponines. This leads to a reflexive increase of bronchial secretion, increasing the quantity of bronchial mucus and decreasing its viscosity

In addition, data are available from two controlled clinical studies comparing Bronchicum Elixir (a combination of thyme liquid extract and primula root liquid extract to Bronchicum drops (a combination of thyme liquid extract and primula root tincture). In a placebo-controlled clinical study with Bronchicum drops, the efficacy of this preparation compared to placebo was demonstrated in patients with acute bronchitis. In this study, the combination of thyme liquid extract and primula root tincture was significantly superior to the placebo solution in all the bronchitis parameters tested (coughing, sputum, rhonchi, chest pain when coughing, dyspnea). In another controlled clinical study, the efficacy of Bronchicum Elixir was compared to that of Bronchicum drops in patients with acute bronchitis. In this controlled clinical study using both test preparations, a significant improvement in the illness was demonstrated both with regards to the primary target criterion (bronchitis severity score, BSS and with regards to all secondary target criteria tested, which was comparable to the results of the verum group in the placebo-controlled study both in terms of manifestation and temporal development. In this study, no significant statistical differences in efficacy between the two test preparations in either the primary or secondary target criteria occurred, so that comparable efficacy could be demonstrated for Bronchicum Elixir and Bronchicum drops.

5.2 Pharmacokinetic properties

Pharmacokinetic studies of herbal preparations made from *Thymi herba* and primula root are not available.

5.3 Preclinical safety data

For the medically active substances, there are only results for the thyme oil contained in *Thymi herba*. The LD₅₀ for the thyme oil contained in the *Thymi herba* (rats, oral) ranges from 2.8 g to 4.7 g per kg bodyweight

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Invert sugar syrup, caramel syrup, sodium benzoate, purified water.

6.2 Shelf life

2 years.

6.3 Special precautions for storage

Store at temperature not exceeding 30 °C.

6.4 Nature and contents of container

Carton box containing amber glass hydrolytic class III bottle with PP plastic cap & PE ring & laminated LDPE from both sides foam liner (containing 100 ml solution) and inner leaflet

6.5 Special precautions for disposal

No special requirements.

Marketing Authorization Holder

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