SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Bronchiclear® oral liquid

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Fluid extract derived from ivy leaves (1:1); (extracting agent: ethanol 70% (V/V)) 16.8 mg/ml.
Fluid extract derived from thyme herb (1:2-2.5); (extracting agent: ammonia solution 10% (m/m): glycerol 85% (m/m): ethanol 90% (V/V): water (1:20:70:109)) 168 mg/ml

The medicinal product contains 7 % (V/V) alcohol.
Contains maltitol, liquid.

Refer to section 6.1 for a complete list of excipients.

3. PHARMACEUTICAL FORM

Liquid for oral administration

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Herbal medicinal product for the relief of symptoms of acute bronchitis with productive cough in the course of a cold, in adults.

4.2 Posology and method of administration

Unless prescribed otherwise, 5.4 ml of Bronchiclear® oral liquid should be taken three times daily. Use the enclosed measuring cup.

Bronchiclear® oral liquid should be swallowed undiluted. If needed, the patient may drink some liquid (preferably glass of water, no alcohol) after taking the medication.
If the patient has a sensitive stomach, the patient should take Bronchiclear® oral liquid after meals.

The treatment duration depends on the course of the disease (see also information in the sections "Special warnings and precautions for use" and "Undesirable effects").

4.3 Contraindications

Do not take Bronchiclear® oral liquid in case of a known hypersensitivity to the active substances or to any of the excipients listed in section 6.1. or to plants of the aralia family, other Lamiaceae (Labiatae), birch, mugwort, and celery.

4.4 Special warnings and precautions for use

The package leaflet informs the patient as follows:
Consult a doctor if complaints persist for more than a week or if symptoms such as dyspnea, fever or purulent and bloody sputum are observed.

Paediatric population:
Bronchiclear® oral liquid is not indicated for children and adolescents under 18 years old.
The medication contains 7 % (V/V) alcohol.

Patients with the rare hereditary fructose intolerance should not take Bronchiclear® oral liquid.

4.5 Interaction with other medicinal products and other forms of interaction

Currently there are no known interactions with other medicinal products.
Studies with Bronchiclear® oral liquid on possible interactions with simultaneously administered medicinal products are not available.

4.6 Pregnancy and lactation

There are no adequate data available on the use in pregnant and lactating women.
Bronchiclear® oral liquid should not be taken by pregnant and lactating women.

4.7 Effects on ability to drive and use machines

This medicinal product contains 7% (V/V) alcohol. A healthy person with a normal body weight metabolises the amount of alcohol that is ingested with a single dose within a few minutes. Effects on the ability to drive and operate machinery are not to be expected.

4.8 Undesirable effects

Like any other medication, Bronchiclear® oral liquid may have undesirable effects.

The frequency rates of undesirable effects are based on the following categories:

very common (≥ 1/10)
common (≥ 1/100 to < 1/10)
uncommon (≥ 1/1.000 to < 1/100)
rare (≥ 1/10.000 to < 1/1.000)
very rare (<1/10.000)
not known (frequency can not be estimated on the basis of available data)

In rare cases: hypersensitivity reactions with skin rash have been observed. Furthermore, hypersensitivity reactions with dyspnea, hives and swellings in face, mouth and/or pharyngeal region may occur.
Gastrointestinal complaints such as cramps, nausea and vomiting are uncommon.

At the first signs of any hypersensitivity reaction Bronchiclear® oral liquid must not be taken again.

Reporting of suspected adverse reactions

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. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form:

https://sideeffects.health.gov.il

Or In addition, suspected adverse events can be reported directly to Dr. Samuelov's drug safety department at: drugsafety@drsamuelov.co.il

4.9 Overdose

In case of extreme overdose, gastric complaints, vomiting and possibly diarrhea may occur.

Upon ingesting large quantities of ivy leaves gastroenteritis may occur due to saponins. So far, only reports about children who ingested fresh ivy leaves are available. Published data from poison centers show that ingestion of 1-5 ivy leaves, in rare cases of up to 10 fresh ivy leaves and fruit caused vomiting and diarrhea in 10% of 301 children. Primary toxin removal and administration of charcoal is recommended for toddlers who have ingested 2 or more fresh ivy leaves. These data cannot be used to draw any conclusions regarding the effects of a dose from a preparation of dried ivy leaves that is used in this medicinal product.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: herbal medicinal product for respiratory cold diseases

ATC-Code: R05CA

The results from in-vitro studies and animal studies with preparations from thyme herb and thyme oil or its main component thymol suggest weak expectorating and spasmolytic effects.

The expectorating effects of thyme herb are probably due to a stimulation of the bronchial ciliated epithelium that is triggered by a reflectory stimulation of the Nervus vagus via the gastric mucosal membrane and resorption as a result of pulmonal secretion via a direct stimulation of serous glandular cells.

The expectorating effects of ivy leaves are probably due to a stimulation of the gastric mucous membrane that is triggered by a reflectory stimulation of sensory fibers of the parasympathetic nervous system in the bronchial mucous membrane.

There are no data available on the pharmacological effects in humans neither for individual components nor the fixed combination.

5.2 Pharmacokinetic properties

There are no data available on pharmacokinetics and bioavailability with preparations from thyme herb and ivy leaves.

5.3 Preclinical safety data

The toxicity of Thymi herba is low; the LD_{50} for the essential oil that is found in a concentration of approx. 1.2 % varies from species to species between 1.98 g/kg and 4.7 g/kg. LD_{50} (mouse) of the total extract amounts to 34 ml/kg.

Toxicity of Hederae helicis folia is low if administered perorally. LD_{50} amounts to more than 3 g extract per kg body weight in mice and significantly more than 4.1 g in rats. A reversible increase of hematocrit levels but no organ-specific changes were observed in a subchronic toxicity study with up to 750 mg/kg ivy extract administered over a period of three months.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified water; maltitol, liquid; hydroxypropylbetadex; potassium sorbate; citric acid monohydrate**.**

Note for diabetics:

1 single dose of Bronchipret® oral liquid (5.4 ml) contains an average of 1.9 g of carbohydrates.

6.2 Incompatibilities

None known.

6.3 Shelf life

The expiry date of the product is indicated on the packaging.

After opening the bottle, use medicine within 6 months.

Do not use the medicine after the expiry date.

6.4 Special precautions for storage

Do not store above 25°C. Store in upright position
Keep out of reach and sight of children!

6.5 Nature and contents of containers

Package with 100 ml liquid for oral administration

6.6 Special precautions for disposal

No special precautions.

7. MANUFACTURER

BIONORICA SE
Kerschensteinerstraße 11-15
92318 Neumarkt
Germany

8. ISRAELI MARKETING AUTHORIZATION HOLDER AND IMPORTER

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Phone: 09 7483769

9. MARKETING AUTHORISATION NUMBER(S)

167-69-35940-00

10. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

June 2021

11. DATE OF REVISION OF THE TEXT

June 2021

12. MARKETING RESTRICTIONS

Over the counter, Available only in pharmacies

Bronchiclear oral liquid-SPC 06/21