

Patient Package Insert according to Pharmacists'
Regulations (Preparations) - 1986
This medicine can be sold without a doctor's prescription

Bronchiclear® oral liquid

Active ingredients and its quantity in 1 ml:

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.

For a list of all inactive ingredients and allergens in the medicine - see section 6.

For important information about some of the ingredients of the medicine - see section 2.

Read this entire leaflet carefully before using this medicine.

This leaflet contains concise information about the medicine. If you have any further questions, refer to the doctor or pharmacist.

The medicine Bronchiclear® oral liquid is intended for adults.

You should take the medicine according to the instructions in the dosage section in this leaflet.

Consult the pharmacist if you need further information.

Refer to the doctor if symptoms of the illness worsen or do not improve after 7 days of using the medicine.

1. What is the medicine intended for?

Herbal medicinal product for use in adults, to relieve the symptoms of acute bronchitis (acute inflammation of the bronchi) during a cold, which is accompanied by a cough and mucus.

Therapeutic group: A herbal medicinal product for respiratory illnesses due to a cold.

2. Before using the medicine:

⚠ Do not use the medicine:

- if you are hypersensitive (allergic) to one or more of the active ingredients or to any of the additional ingredients contained in the medicine. The list of additional ingredients is detailed in section 6.
- if you are hypersensitive (allergic) to plants from the aralia family, plants of the labiates family (lamiaceae or labiates), birch plant, mugwort plant, or celery plant.

Special warnings regarding the use of this medicine:

- Refer to a doctor if symptoms of the illness worsen or do not improve after 7 days of using the medicine.
- Refer to the doctor immediately in any case of shortness of breath, fever, bloody or purulent expectoration.

Children and adolescents: The medicine is not intended for use in children and adolescents under 18 years of age.

If you are taking or have recently taken any other medicines including non-prescription medicines and nutritional supplements, tell your doctor or pharmacist. There are no known interactions between the medicine Bronchiclear® oral liquid and other medicines.

Use of this medicine and food: The medicine Bronchiclear® oral liquid may be taken with food, with drinks or without connection to food.

For further information, see section 3 – "How to use this medicine".

Pregnancy and breastfeeding: Since there is insufficient information, do not use the medicine Bronchiclear® oral liquid if you are pregnant or if you are breastfeeding.

Driving and use of machinery: There are no warnings or special guidelines on the use of Bronchiclear® oral liquid while driving or operating machinery.

Important information about some of the ingredients of this medicine:

The medicine Bronchiclear® oral liquid contains maltitol.

Consult a doctor before using the medicine Bronchiclear® oral liquid if you have been told by your doctor that you have an intolerance to certain sugars.

Information for diabetics: 5.4 ml Bronchiclear® oral liquid contains an average of 1.9 grams of carbohydrate.

The medicine Bronchiclear® oral liquid contains 7% alcohol by volume.

3. How to use this medicine

Check with your doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

The usual recommended dosage is:

Age	Single dose in ml (take x 3 every day)	Total daily dose
Adults 18 years of age and older	5.4 ml	16.2 ml





Do not exceed the recommended dose.

Duration of treatment: The duration of treatment depends on the course of the illness. Refer to a doctor as soon as possible if the symptoms of the illness worsen or do not improve after 7 days of using the medicine.

Method of administration: Take the medicine Bronchiclear® oral liquid using the enclosed measuring cup 3 times a day (morning, noon and evening) directly by mouth. You may drink some liquid as necessary (preferably a glass of water), not an alcoholic beverage, after taking the medicine. If you have a known sensitivity of the digestive system, it is recommended to take the medicine Bronchiclear® oral liquid after meals. Shake before use.

If you have accidentally taken a larger dosage you must inform your doctor, he/she will decide whether any further measures are necessary. In a case of overdose, there may be abdominal pain, vomiting or diarrhea. If a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine at the intended time, do not take a double dose. Take the next dose at the usual time and consult a pharmacist or doctor.

If you stop taking the medicine: Stopping the treatment usually does no harm.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them. If you have any further questions regarding the use of this medicine, consult a doctor or pharmacist.

4. Side effects

As with any medicine, the use of Bronchiclear® oral liquid can cause side effects in some users.

Do not be alarmed while reading the list of side effects, you might not suffer from any of them.

If one of the listed side effects appears, stop using the medicine Bronchiclear® oral liquid and consult a doctor as soon as possible. The doctor will determine the severity of the side effect and decide whether any further measures are necessary.

Rare side effects that occur in 1-10 users of the medicine out of 10,000:

Stop using the medicine and proceed to a doctor or emergency room upon appearance of the first sign of hypersensitivity (allergic reaction) such as: skin reaction (urticaria, rash or itching), shortness of breath, swelling of the face, mouth and/or throat.

Uncommon side effects occur in 1-10 users of the medicine out of 1000:

Discomfort in the digestive system such as cramps, nausea, vomiting.

If a side effect appears, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the home page of the Ministry of Health's website (www.health.gov.il), which refers to the online form for reporting side effects or via the following link: <https://sideeffects.health.gov.il> Additionally, side effects can be reported to Dr. Samuelov Importing & Marketing Ltd. at the e-mail address: drugsafety@drsamuelov.co.il

5. How to store the medicine

Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach of children and/or infants to avoid poisoning.

Do not induce vomiting unless explicitly instructed to do so by the doctor.

Do not use the medicine after the expiry date (Exp. date) stated on the carton or the bottle.

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

Storage conditions: Do not store above 25°C. Keep the bottle in a vertical position.

Do not place on its side or upside down.

Shelf life after first opening: 6 months

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6. Additional information

In addition to the active ingredient, the medicine also contains the following inactive ingredients:

Purified water, maltitol liquid, hydroxypropylbetadex, potassium sorbate, citric acid monohydrate

What the medicine looks like and what the package contains: The medicine Bronchiclear® oral liquid looks like a light brown clear liquid.

Package size: The medicine Bronchiclear® oral liquid comes in a carton containing a brown 100 ml glass bottle with a measuring cup.

Approved in June 2021.

Registration holder and importer: Dr. Samuelov Importing & Marketing Ltd., P.O.B 2486, Ra'anana 4365007, Tel.: 09-7483769, E-mail address: info@drsamuelov.co.il.

Manufacturer: Bionorica SE, Kerschensteinerstr. 11-15, Neumarkt 92318, Germany.

Drug registration number in the national medicine registry of the Ministry of Health: 167-69-35940-00

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