

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

## Bronchiclear® tablets

**Active ingredients and their quantity in dosage unit:**  
**Each film-coated tablet contains:**  
60 mg dry extract of primula root (6-7:1); extracting agent: ethanol 47.4% (V/V)  
160 mg dry extract of thyme herb (6-10:1); extracting agent: ethanol 70% (V/V).

For a list of all excipients 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, ask the physician or pharmacist.  
The medicine Bronchiclear® tablets is intended for adults, adolescents and children over 12 years of age. Take the medicine according to the instructions in the dosage section of this leaflet.  
Consult your pharmacist if you need further information.

Refer to your physician if symptoms of the illness worsen or do not improve after 10 days of use of the medicine.

### **1. What is the medicine intended for?**

The medicine Bronchiclear® tablets is intended for the relief of symptoms in acute bronchitis with coughs and colds associated with viscous mucus, in adults, adolescents and children over 12 years of age.

Bronchitis is also referred to as inflammation of the bronchi of the respiratory tracts.

**Therapeutic group:** expectorant

### **2. Before using the medicine** **Do not use the medicine if:**

You are hypersensitive (allergic) to one or more of the following active ingredients: Primula, Thyme, other plants from the Lamiaceae or Labiates family, Birch, Mugwort, Celery or to any of the additional ingredients that the medicine contains. Additional ingredients are listed in section 6.
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### **Special warnings regarding the use of this medicine:**

- Refer to your physician if symptoms of the illness worsen or do not improve after 10 days of use of the medicine.
- Refer to your physician immediately in case of shortness of breath, fever, bloody or purulent sputum.
- If you suffer from gastritis or an ulcer, take the medicine Bronchiclear® tablets after meals with a glass of water.

**Children and adolescents:** Do not use the medicine Bronchiclear® tablets in children under 12 years of age since there is insufficient information regarding the use of this medicine in this age group.

**Drug interactions: If you are taking or have recently taken any other medicines, including non-prescription medicines and nutritional supplements, tell your physician or pharmacist.** There are no known interactions between Bronchiclear® tablets and other medicines to date. There is no information regarding the potential of interactions between Bronchiclear® tablets and other medicines that are taken simultaneously.

**Use of this medicine and food:** Take the medicine Bronchiclear® tablets before meals, with a sufficient amount of drinkable liquid (a glass of water is preferable).

**Pregnancy and breastfeeding:** If you are pregnant, breastfeeding, think you may be pregnant or are

planning on becoming pregnant, consult your physician or pharmacist before using the medicine Bronchiclear® tablets. Since there is insufficient information, do not use the medicine Bronchiclear® tablets if you are pregnant or if you are breastfeeding.

**Fertility:** There is insufficient information regarding the effect of the medicine Bronchiclear® tablets on fertility in humans. In studies done on animals, no adverse effects on fertility as a result of using the medicine Bronchiclear® tablets were observed.

**Driving and use of machinery:** There are no special precautions or instructions regarding the use of the medicine Bronchiclear® tablets while driving or using machinery.

### **Important information about some of the ingredients of this medicine:**

The medicine Bronchiclear® tablets contains glucose and lactose. Consult your physician before using the medicine Bronchiclear® tablets if you have an intolerance to certain sugars.

Information for diabetics: a single film-coated tablet of Bronchiclear® tablets contains an average of 0.2 grams carbohydrate. The medicine Bronchiclear® tablets is gluten free.

### **3. How to use this medicine**

Check with your physician or pharmacist if you are not sure.

**The usual recommended dosage for adults, adolescents and children over 12 years of age is:** One film-coated tablet of Bronchiclear® tablets, 3 times daily. **Do not exceed the recommended dose.**

### **Administration method of the medicine**

#### **Bronchiclear® tablets:**

Take the film-coated tablet before meals, with a sufficient amount of drinkable liquid (e.g. a glass of water).

**Crushing/halving/chewing:** Do not crush or chew or halve the film-coated tablet.

### **Duration of treatment with the medicine**

**Bronchiclear® tablets:** Duration of treatment depends on the course of the illness. Refer to your physician immediately if symptoms do not improve after 10 days of use of the medicine.

**If you have accidentally taken an overdose** inform your physician. Your physician will decide whether it is necessary to take any action. In the event of an overdose, stomach aches, vomiting or diarrhea may occur. If a child has accidentally swallowed the medicine, proceed immediately to a physician or a hospital emergency room and bring the package of the medicine with you.

**If you forgot to take this medicine** at the intended time, do not take a double dose. Take the next dose at the regular time and consult your pharmacist or physician.

**If you stop taking the medicine:** Discontinuation of the treatment is usually not accompanied by withdrawal effects or special symptoms.

**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 your physician or pharmacist.**

### **4. Side effects**

As with any medicine, the use of Bronchiclear® tablets may 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 side effects listed below appears, stop taking the medicine Bronchiclear® tablets and consult your physician as soon as possible. Your physician will decide on the severity of the side effect and whether it is necessary to take any action.

### **Side effects that require special attention:**

**The frequency of the following side effects is very**

**rare and appears in less than 1 user out of 10,000:** Stop taking the medicine and refer to a physician or a hospital emergency room at the first sign of hypersensitivity (allergic reaction) such as shortness of breath, urticaria, swelling of the face, mouth and/or throat.

### **Uncommon side effects that appear in 1-10 users of the medicine out of 1000:**

Discomfort and gastrointestinal disturbances such as cramps, nausea, vomiting and diarrhea. **If a side effect appears, if any of the side effects gets worse, or if you suffer from a side effect not mentioned in the leaflet, consult your physician.**

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" that can be found on the home page of the Ministry of Health's website ([www.health.gov.il](http://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](mailto:drugsafety@drsamuelov.co.il).

### **5. How to store the medicine**

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

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

Do not use the medicine after the expiry date (exp. date) stated on the carton package and/or blister. The expiry date refers to the last day of that month. Storage conditions: Do not store above 25°C.

### **6. Additional information**

**In addition to the active ingredient, the medicine also contains the following excipients:**

Chlorophyllin preparation (25% copper chlorophyllin, 75% dextrose) (E141), crospovidone, dimethicone,

glucose liquid spray-dried, colloidal anhydrous silica, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, peppermint flavour, polyacrylate dispersion 30%, povidone K25, propylene glycol, riboflavin (E101), saccharin sodium, talc, titanium dioxide (E171).

### **What the medicine looks like and contents of the package:**

The medicine Bronchiclear® tablets is a green, round, biconvex, film-coated tablet with a semi-matt surface and no score line. The film-coated tablets are packed in blisters, which are packaged in carton boxes.

**Size of package:** The medicine Bronchiclear® tablets is supplied in a carton package containing a blister with 20 film-coated tablets.

### **Registration holder and importer:**

Dr. Samuelov Importing & Marketing Ltd.,  
Company ID 512260944 P.O.B 2486, Ra'anana 4365007.

Tel.: 09-7483769, e-mail address: [info@drsamuelov.co.il](mailto:info@drsamuelov.co.il).

**Manufacturer:** Bionorica SE, Neumarkt 92318, Germany.

The format of this leaflet was determined by the Ministry of Health and its content checked and approved in October 2017

**Drug registration number in the national medicine registry of the Ministry of Health:** 159-49-34894-00

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