

**Patient Package Insert according to  
Pharmacists' Regulations (Preparations) - 1986**

This medicine can be sold without a physician's prescription

# Sinuclear® extract tablets

## Coated tablets

### Active ingredients and their quantity in dosage unit:

#### Each coated tablet contains:

160 mg native dry extract (3-6:1) derived from gentian root, primula flowers, sorrel herb, elder flowers, verbena herb (1:3:3:3:3)

1. extracting agent: ethanol 51% (m/m)

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.

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 7-14 days of use of the medicine.

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

Herbal medicinal product for the symptomatic relief of nasal congestion and headaches in those suffering from acute uncomplicated inflammations of the paranasal sinuses (acute uncomplicated rhinosinusitis) in adults and children from the age of 12 years.

**Therapeutic group:** Herbal medicine for the treatment of rhinosinusitis.

### **2. Before using the medicine**

#### **Do not use the medicine:**

- If you are hypersensitive (allergic) to one or more of the following plants: Verbena, Gentian, Sorrel, Elder, Primula or to any of the additional ingredients that the medicine contains. Additional ingredients are listed in section 6.
- If you suffer or have suffered in the past from a stomach and/or intestinal ulcer.

#### **Special warnings regarding the use of this medicine:**

Refer to your physician if symptoms of the illness worsen or do not improve after 7-14 days or if the symptoms recur and/or if you experience persistent fever, severe pain or unexplained discomfort.

This medicine should be used carefully by patients who suffer from stomach inflammation or in cases of sensitive stomach. In such cases it is recommended to take the medicine Sinuclear® extract tablets after a meal with a glass of water.

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

**If you are taking or have recently taken any other medicines, including non-prescription medicines and nutritional supplements, tell your physician or pharmacist.** No studies have been conducted to assess the effect of the medicine Sinuclear® extract tablets on other medicines, therefore it cannot be ruled out that the effect of other medications may be increased or decreased. Taking the medicine Sinuclear® extract tablets concurrently with medicines that have a narrow therapeutic range should be done only after evaluating

the specific case and consulting the attending physician.

**Use of this medicine and food:** The medicine Sinuclear® extract tablets can be taken with food, beverages, or independently of food.

If you have any known sensitivity in your digestive system, it is recommended to take the medicine Sinuclear® extract tablets after meals.

#### **Pregnancy and breastfeeding:**

If you are pregnant or breastfeeding, think you are pregnant or are planning a pregnancy, consult a pharmacist or physician before using the medicine Sinuclear® extract tablets. There is no information about the use of the medicine during pregnancy. As a precaution, avoid using the medicine during pregnancy. Since it is not known whether the active ingredients of the medicine pass into breast milk, risks to the infant cannot be ruled out. Do not use the medicine during breastfeeding.

**Driving and use of machinery:** The medicine Sinuclear® extract tablets might have a small effect on the ability to drive or use machinery in patients who might experience the side effect "dizziness" (see section 4).

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

The medicine Sinuclear® extract tablets contains glucose and sucrose. Consult a physician before using the medicine Sinuclear® extract tablets if you have intolerance to certain sugars.

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

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

**The usual recommended dosage for adults and children over 12 years of age is:** One

coated tablet of Sinuclear® extract tablets, 3 times daily (morning, noon and evening). There are insufficient data for specific dosage recommendations in patients with impaired kidney/liver function.

**Do not exceed the recommended dose.**

**Administration method of the medicine Sinuclear® extract tablets:** Swallow the coated tablet with a drinkable liquid (for example a glass of water).

See above 'Use of this medicine and food'.

Crushing/halving/chewing: do not crush or chew or halve the coated tablet, as this may damage the coating of the medicine.

**Duration of treatment with the medicine Sinuclear® extract tablets:** Unless instructed otherwise by the physician, the duration of use is 7 to 14 days.

Refer to a physician if symptoms of the illness worsen or do not improve after 7-14 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. 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. In the event of an overdose, it is possible that the side effects listed below (nausea, abdominal pain, diarrhea) may appear in a more intense form.

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

**If you stop taking the medicine:**

Discontinuation of the treatment is not usually accompanied by 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 Sinuclear® extract 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.

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

Discontinue use of the medicine and refer immediately to a physician or hospital emergency room at first sign of a severe allergic reaction characterized by swelling of the lips, swelling of the tongue, swelling of the throat and/or pharynx accompanied by narrowing of the respiratory tract, shortness of breath and swelling of the face.

Stop the use and do not use the medicine again with the appearance of a local allergic reaction such as: rash, skin redness, itching of the skin and eyes.

The frequency of these side effects is rare.

#### **Common side effects: appear in 1-10 users of the medicine out of 100:**

Discomfort in the digestive system such as: nausea, flatulence (gas), diarrhea, dry mouth, abdominal pain.

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

Dizziness.

**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 a 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 reporting side effects, or via the following link: <https://sideeffects.health.gov.il> In addition, side effects can be reported to Dr. Samuelov Importing & Marketing Ltd. at the email 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 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 ingredients, the medicine also contains the following excipients:**

Sucrose, talc, calcium carbonate, microcrystalline cellulose, maltodextrin, cellulose; powdered, hypromellose, dextrin, acacia spray dried, silica; colloidal anhydrous, silica; hydrophobic colloidal, titanium dioxide (E 171), glucose liquid, magnesium stearate, stearic acid 50, chlorophyll powder 25% (E 141), indigo carmine aluminium lacquer (E 132), carnauba wax, riboflavin (E 101).

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

The medicine Sinuclear® extract tablets is a round, convex, green coated tablet with a smooth surface and no score line.

The coated tablets are packed in plastic trays ("blisters"), which are packaged in carton boxes.

**Size of package:** The medicine Sinuclear® extract tablets is supplied in carton packages containing 20 coated tablets (2 blisters with 10 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, 11-15  
Kerschensteinerstr., Neumarkt 92318,  
Germany.

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**Drug registration number in the national medicine registry of the Ministry of Health:**  
177-48-36980-00

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