

Patient Package Insert according to Pharmacists' Regulations (Preparations), 1986.

This medicine can be sold without a physician's prescription

Sinuclear Coated tablets

Active ingredients and their quantity in dosage unit:

Each coated tablet contains:

Verbena herb, powdered 36 mg; Gentian root, powdered 12 mg; Common Sorrel herb, powdered 36 mg; Elder flower, powdered 36 mg; Primula flower with calyx, powdered 36 mg.

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 Sinuclear is intended for adults 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 7-14 days of use or if the symptoms recur.

1. What is the medicine intended for?

The medicine Sinuclear is intended to provide relief of symptoms in the nose and its sinuses in connection with common cold, in adults and children older than 12 years. These symptoms include: nasal congestion, runny nose, headache and facial pain around the sinuses.

Therapeutic group: herbal medicine for the treatment of the common cold.

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, Common Sorrel, Elder, Primula or to any of the additional ingredients that the medicine contains. Additional ingredients are listed in section 6.
--

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.

⚠ Children and adolescents: do not use Sinuclear 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. So far, there are no known interactions between Sinuclear and other medicines.

⚠ Use of this medicine and food: the medicine Sinuclear can be taken with food, beverages, or independently of food. If you have any known sensitivity

in your digestive system, it is recommended that you take the medicine Sinuclear after meals.

⚠ Pregnancy and breastfeeding: if you are pregnant or breastfeeding, consult your pharmacist or physician before using the medicine Sinuclear. As with other medicines, the use of Sinuclear during pregnancy or breastfeeding must only be done after a risk-benefit evaluation has been made by the attending physician.

⚠ Driving and use of machinery: there are no special precautions or instructions regarding the use of the medicine Sinuclear while driving or using machinery.

⚠ Important information about some of the ingredients of this medicine:

The medicine Sinuclear contains glucose, lactose, sucrose and sorbitol.

Consult your physician before using the medicine Sinuclear if you have intolerance to certain sugars.

Information for diabetics: a single coated tablet of Sinuclear contains 0.2 grams of carbohydrate on average. The medicine Sinuclear does not contain gluten.

3. How to use this medicine

Check with your physician or pharmacist if you are not sure. **The usual recommended dosage for adults and children over 12 years of age is:** one coated tablet of Sinuclear, 3 times daily. **Do not exceed the recommended dose.**

Administration method of the medicine Sinuclear:

take one coated tablet of Sinuclear 3 times daily (morning, noon and evening). Take the coated tablet with a drinkable liquid (e.g. a glass of water).

Crushing/halving/chewing: do not crush or chew or halve the coated tablet.

Duration of treatment with the medicine Sinuclear: unless instructed otherwise by your physician, the duration of use is 7 to 14 days. Refer to your physician if symptoms of the illness worsen or do not improve after 7-14 days of use or if the symptoms recur.

If you have taken an overdose inform your physician immediately. Your physician will decide whether it is necessary to take any action.

If a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.

In the event of an overdose, it is possible that side effects caused by use of the medicine will be more intense.

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 not usually 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 Sinuclear 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

your physician or hospital emergency room at first sign of an acute 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 (angioedema), shortness of breath and swelling of the face. The frequency of these side effects is rare.

Uncommon side effects: appear in 1-10 users out of 1,000:

Discomfort in the digestive system (stomachache, nausea).

Rare side effects: appear in 1-10 users out of 10,000:

Allergic reactions of the skin such as rash, redness and itching.

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), 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

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.

Storing conditions: Do not store above 25°C.

6. Additional information

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

Sucrose, talc, lactose monohydrate, calcium carbonate, potato starch, maize starch, dextrin, silica (colloidal anhydrous), stearic acid, titanium dioxide, liquid glucose, gelatin, shellac, light magnesium oxide, sorbitol, basic butylated methacrylate copolymer, montan glycol wax. Riboflavin (E101), indigo carmine (E132), aluminium hydroxide, cuprum chlorophylline (E141), castor oil (refined).

What the medicine looks like and contents of the package:

The medicine Sinuclear is a round, convex, green coated tablet with a smooth surface and no score line. The coated tablets are packed in blisters, packaged in carton boxes.

Size of package: The medicine Sinuclear is supplied in carton packages containing a blister with 20 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.

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 May 2017.

Drug registration number in the national medicine registry of the Ministry of Health: 158-57-34682-00

Sinuclear PIL PB1221-02