

**Patient Package Insert in Accordance with the Pharmacists' Regulations
(Preparations) -1986**

The medicine is sold without a doctor's prescription

Sinuclear® Syrup

Active ingredients and their quantity per dosage unit:

1 ml syrup contains: 417 mg extract (1:38.5) from 0.011 g of a mixture of gentian root, verbena herb, common sorrel herb, elder flower, primula flower with calyx (1:3:3:3:3);
1. extracting agent: ethanol 59% (V/V), 2. - 4. extracting agent: purified water.

For a list of all inactive and allergenic substances in the medicine - see section 6.

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

Carefully read the leaflet to the end before using the medicine.

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

The medicine Sinuclear® Syrup 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 a pharmacist if you need more information.

Consult a doctor if the signs of the disease (symptoms) worsen or do not improve after 7-14 days of using the medicine.

1. What is the medicine intended for?

The medicine Sinuclear® Syrup is intended to provide relief of symptoms in the nose and its sinuses in connection with common cold, in adults and children over 12 years of age.

These symptoms include: nasal congestion, runny nose, headache and facial pain around the sinuses.

Therapeutic group: Herbal medicine for the treatment of colds.

2. Before using the medicine:

Do not use the medicine:

- if you are hypersensitive (allergic) to one or more of the active substances or to any of the additional ingredients that the medicine contains. The list of additional ingredients is detailed in section 6.

Special warnings regarding the use of the medicine:

- Consult a doctor if the symptoms of the disease worsen or do not improve after 7-14 days of using the medicine or if the symptoms of the disease are recurring.
- Refer to a doctor if you experience symptoms such as: high fever, nosebleeds, sharp pain, purulent nasal discharge, visual disturbance, asymmetry between parts of the face or in the eye area, or numbness in the face area.
- If you suffer from inflammation of the stomach (gastritis) or a known sensitivity in the digestive tract, you must take the medicine Sinuclear® Syrup after a meal together with a glass of water.

Children and adolescents: This medicine is not intended for children and adolescents under the age of 12, as there is no information about the safety and efficacy of the use of this medicine in children under this age.

If you are taking or have recently taken any other medicines, including non-prescription medicines and dietary supplements, tell the doctor or pharmacist. There are no known interactions between the medicine Sinuclear® Syrup and other medicines.

Use of the medicine and food: The medicine Sinuclear® Syrup can be taken with food, with drink or without food.

For more information, see Chapter 3 – "How to use the medicine".

Pregnancy, breastfeeding and effect on fertility:

If you are pregnant, breastfeeding, think you are pregnant or planning a pregnancy, consult a doctor or pharmacist before taking the medicine.

The use of the medicine Sinuclear® Syrup during pregnancy or breastfeeding is to be done only under the guidance of the doctor, after evaluating the benefit against the risk in these cases. Since the medicine Sinuclear® Syrup contains alcohol, the use of Sinuclear® tablets is preferable during pregnancy or breastfeeding. There is insufficient information regarding the effect of the medicine on human fertility.

Driving and operating machinery: There are no special warnings or instructions regarding the use of the medicine Sinuclear® Syrup while driving or operating machinery.

Important information about some of the ingredients of the medicine:

The medicine Sinuclear® Syrup contains liquid maltitol. The medicine Sinuclear® Syrup contains 8% alcohol by volume.

This medicine contains 64 mg of alcohol (ethanol) in each 1 ml of syrup, equivalent to 8% alcohol by volume.

The maximum amount of alcohol (ethanol) in one 7 ml dose of syrup is equivalent to 12 ml of beer or 5 ml of wine. This small amount of ethanol has no effect and does not require special attention.

Consult a doctor before using the medicine Sinuclear® Syrup if you have been told by your doctor that you suffer from an intolerance to certain sugars.

Information for diabetics: 7 ml of Sinuclear® Syrup contains 5.5 grams of liquid maltitol, equivalent to about 0.35 carbohydrate exchange units or 12.65 calories.

Liquid maltitol may have a mild laxative effect.

3. How to use the medicine?

You should check with the doctor or pharmacist if you are not sure about the dosage and the method of using the preparation.

The usual dose is:

Age	Single dose in ml (take 3 x daily)	Total daily dose
Adults and children 12 years of age and older	7 ml	21 ml

Do not exceed the recommended dose.

There is no information about the exact dosage in patients suffering from impaired kidney function or liver dysfunction.

Duration of treatment: Unless you have received other instructions from the doctor, the duration of treatment with this medicine is 7-14 days.

Refer to a doctor if the symptoms of the disease worsen or do not improve after 7-14 days of using the medicine.

Method of administration: Take the medicine Sinuclear® Syrup directly into the mouth 3 times a day (morning, noon and evening) using the included measuring cup. If necessary, drink a little fluid (preferably a glass of water) and not an alcoholic drink, after taking the medicine.

If you have a known sensitivity in the digestive system, it is recommended to take the medicine Sinuclear® Syrup after meals.

Shake before use.

If you have accidentally taken a higher dosage inform your doctor, they will decide if it is necessary to take any action. In case of taking an overdose, the side effects listed in section 4 may be stronger. If a child accidentally swallows the medicine, proceed to a doctor or hospital emergency room immediately and bring the medicine package with you.

If you forgot to take the medicine at the designated 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 is usually not harmful.

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

4. Side effects

As with any medication, the use of Sinuclear® Syrup may cause side effects in some users.

Don't be alarmed when reading the list of side effects, you may not suffer from any of them.

If one of the side effects listed below has occurred, stop using the medicine Sinuclear® Syrup and consult a doctor as soon as possible. The doctor will determine the severity of the side effect and decide if it is necessary to take any action.

Side effects that require special attention:

Stop using the medicine and proceed immediately to a doctor or emergency room at the 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 airways (angioedema), shortness of breath and swelling of the face. The frequency of these side effects is unknown.

Uncommon side effects that occur in 1 to 10 users out of 1,000:

Discomfort in the digestive system (abdominal pain, nausea).

Allergic skin reactions (rash, redness, itching).

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

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting side effects of medication" found on the home page of the Ministry of Health website (www.health.gov.il), directing to the online form of adverse effects or via the link: <https://sideeffects.health.gov.il>

In addition, you can report a side effect to Dr. Samuelov Import and Marketing at the email address: drugsafety@drsamuelov.co.il

5. How to store the medicine?

Prevent poisoning! This medicine and any other medicine should be kept in a closed place out of the reach of children and/or infants to prevent poisoning.

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

Do not use the medicine after the expiration date (exp. date) that appears on the carton or bottle.

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

Storage conditions: Do not store above 30°C.

Shelf life after first opening: 6 months

Storage conditions after first opening: Do not store above 30°C.

6. Additional information

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

Liquid maltitol, cherry flavour

What the medicine look like and contents of the pack: The medicine Sinuclear® Syrup looks like a clear and dense fluid of light brown color. During storage there may be accumulation of particles and cloudiness of the solution. This has no effect on the effectiveness of the medicine.

The size of the package: The medicine Sinuclear® Syrup is supplied in a carton package containing a 100 ml brown glass bottle with an included measuring cup.

Registration holder and importer: Dr. Samuelov Import and Marketing Ltd., PO Box 2486, Ra'anana 4365007

Phone: 09-7483769, email: info@drsamuelov.co.il

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

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