

Package leaflet:
Information for the user



Sinupret® Syrup

Syrup for oral use

Active substances:
Gentian root, cut
Verbena herb, cut
Common sorrel herb, cut
Elder flower, rubbed
Primula flower with calyx, cut

For use in children from 2 years of age and adults

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to take Sinupret Syrup carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your doctor or pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 7 - 14 days.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Sinupret Syrup is and what it is used for
2. Before you take Sinupret Syrup
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4. Possible side effects
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1. WHAT SINUPRET SYRUP IS AND WHAT IT IS USED FOR

Sinupret Syrup is an herbal medicine for the treatment of inflammations of the paranasal sinuses.

Sinupret Syrup is used for the relief of complaints in acute inflammations of the paranasal sinuses.

2. BEFORE YOU TAKE SINUPRET SYRUP

DO NOT take Sinupret Syrup:

If you are hypersensitive (allergic) to gentian root, verbena herb, common sorrel herb, elder flower, primula flower or to any of the other ingredients of this medicine (see section 6 FURTHER INFORMATION for other ingredients).

Take special care with Sinupret Syrup:

If complaints last longer than 7 - 14 days or return periodically, contact a doctor.

Use in children:

The medicine should not be used in children under 2 years of age.

There are no sufficient investigations to date on the use of Sinupret Syrup in children under 2 years of age.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

There are no known interactions with other medicines up to now.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

As for all medicines, Sinupret Syrup should only be used during pregnancy and breast-feeding after a strict risk-benefit evaluation by the attending doctor. Owing to its alcohol content, Sinupret Syrup should only be taken during pregnancy and breast-feeding if it is not possible to take Sinupret coated tablets.

Driving and using machines

No special precautions are required.

Important information about some of the ingredients of Sinupret Syrup

The medicine contains 8 vol % alcohol.

This medicine contains **maltitol solution**. Please take Sinupret Syrup only after having consulted with your doctor if you know that you have an intolerance against certain sugars. 7.0 ml contain 5.5 g maltitol solution, corresponding to approx. 0.35 carbohydrate exchange units (CEU). Take this into consideration if you are on a diabetes diet. The calorific value is 2.3 kcal/g maltitol solution.

Maltitol solution can have a mild laxative effect.

3. HOW TO TAKE SINUPRET SYRUP

Always take Sinupret Syrup exactly according to the instructions in this leaflet. You should check with your doctor or pharmacist if you are not sure.

If not otherwise prescribed by your doctor, the usual dose is:

Age	Single dose	Total daily dose
Children under the age of 2 years	No application.	
Children from 2 to 5 years	2.1 ml = 2.5 g	6.3 ml = 7.5 g (3 times 2.1 ml)
Children from 6 to 11 years	3.5 ml = 4.2 g	10.5 ml = 12.6 g (3 times 3.5 ml)
Adolescents from the age of 12 years and adults	7.0 ml = 8.4 g	21.0 ml = 25.2 g (3 times 7.0 ml)

Method of administration:

Using the enclosed measuring cup take Sinupret Syrup 3 times daily (morning, midday, evening), undiluted or with some water. If required some liquid (no alcohol), preferably a glass of water, can be drunk afterwards. Sinupret Syrup can be taken with meals, with beverages, or independently of meals. If you have a sensitive stomach, you should best take Sinupret Syrup after meals.

Shake before use!

Duration of administration:

Unless otherwise prescribed, the duration of administration is 7 – 14 days. If you experience no improvement by then please consult a doctor.

If you take more Sinupret Syrup than you should:

If you have taken more Sinupret Syrup than you should, please notify your doctor. He can decide on any necessary measures. It is possible that the side effects listed below may be more intense.

If you forget to take Sinupret Syrup

If you have taken too few Sinupret Syrup or have forgotten to take Sinupret Syrup, do not take a double dose the next time, but rather continue taking it as prescribed by your doctor or as described in this leaflet.

If you stop taking Sinupret Syrup

Discontinuing Sinupret Syrup is usually harmless. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Sinupret Syrup can cause side effects, although not everybody gets them.

The evaluation of possible side effects is based on the following frequency rates:

Very common:

more than 1 out of 10 persons treated

Common:

1 to 10 out of 100 persons treated

Uncommon:

1 to 10 out of 1,000 persons treated

Rare:

1 to 10 out of 10,000 persons treated

Very rare:

less than 1 out of 10,000 persons treated

Not known:

frequency cannot be estimated from the available data

Significant side effects or signs to which you should pay attention, and actions to take if you are affected:

Gastrointestinal complaints (stomach ache, nausea) are **uncommon**.

Hypersensitivity reactions of the skin (rash, reddening, itching) are **uncommon**.

Serious allergic reactions may also occur (swelling of the lips, tongue and throat and/or larynx with narrowing of the airways (angio-oedema), shortness of breath, facial swelling). The frequencies are not known.

At the first signs of a hypersensitivity reaction Sinupret Syrup must not be taken again.

If side effects occur, the medicine should be discontinued and a doctor should be consulted. The doctor can determine the severity and whether any action is necessary.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Bundesinstitut für Arzneimittel und Medizinprodukte [Federal Institute for Drugs and Medical Devices], Abt. Pharmakovigilanz [dept. Pharmacovigilance], Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, website: www.bfarm.de. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE SINUPRET SYRUP

Do not store above 30°C.

Keep out of the reach and sight of children.

Do not use Sinupret Syrup after the expiry date which is stated on the box and the bottle (label). The expiry date refers to the last day of that month.

Information on shelf life after opening:

May be kept for 6 months after opening.

6. FURTHER INFORMATION**What Sinupret Syrup contains:**

100 g (83.3 ml) Sinupret Syrup contain

34.5 g extract (1:38.5) from 0.9 g of a mixture of gentian root, verbena herb, common sorrel herb, elder flower, primula flower with calyx (1:3:3:3:3); 1. extraction solvent: 59 vol % ethanol 2. - 4. extraction solvent: purified water

Contains 8 vol % alcohol.

The other ingredients are:
Maltitol solution, cherry flavour.

What Sinupret Syrup looks like and contents of the pack:

Sinupret Syrup is available in packages containing 100 ml (N1) of syrup. Sinupret Syrup is light-brown, clear, viscous syrup. Slight turbidity or flocculation may occur during storage which has no impact on the effectiveness of the product.

Marketing Authorisation Holder and Manufacturer**BIONORICA SE**

Kerschensteinerstrasse 11-15

92318 Neumarkt

Telephone: +49 (0)9181 231-90

Telefax: +49 (0)9181 231-265

Internet: www.bionorica.de

Email: info@bionorica.de

Co-distributor

PLANTAMED Arzneimittel GmbH

Kerschensteinerstrasse 11-15

92318 Neumarkt

Telephone: +49 (0)9181 231-0

Telefax: +49 (0)9181 218-50

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