

## Patient Leaflet Information

### Sinupret®

**Pharmaceutical form:**

Oral drops and coated tablets

**Trade name:**

Sinupret

**Composition:**

100 g of drops contain: 29 g of aqueous-alcohol extract from the following vulnerary herbs:

Gentiane radix	0.2 g
Primulae flos	0.6 g
Rumicis herba	0.6 g
Sambuci flos	0.6 g
Verbenae herba	0.6 g

Ethanol content: 19% (volume ratio)

Supplemental ingredients: distilled water

One coated tablet contains the following vulnerary herbs:

Gentiane radix	6 mg
Primulae flos	18 mg
Rumicis herba	18 mg
Sambuci flos	18 mg
Verbenae herba	18 mg

Supplemental ingredients:

Calcium Carbonate E 170, Chlorophyllin preparation 25% (E 141), Dextrine, Eudragit E 12.5, Gelatin, Liquid Glucose, Indigo carmine, E 132, Aluminiumoxide, Potato starch, Lactose monohydrate, Maize starch, Light Magnesium Oxide, Montan glycol wax, Riboflavin (E101), Virgin Castor oil, Sucrose, Shellac, Colloidal anhydrous silica, Sorbitol, Stearic acid, Talc, Titanium dioxide, E 171, Distilled water.

**Description:**

**Oral drops:** clear yellowish-brown liquid with bitter taste and aromatic odour. During storage it may form a little sediment.

**Coated tablets:** green, round, biconvex, and smooth surface.

**Pharmacotherapeutic group:**

Secretolytic agent

**Pharmacological properties:**

Combined medication of the phytogenous origin.

Its pharmacological properties are determined by the biologically active substances contained therein. Sinupret is characterized by the secretolytic, secretomotoric and anti-inflammatory

properties. Enables the discharge of exudates from the accessory sinuses of nose and the upper air passages.

**Indications:**

Acute and chronic sinusitis, which is accompanied by thick discharge.

**Contraindications:**

Hypersensitivity to the components of the medication.

**Side effects:**

Gastrointestinal disorders (e.g. stomach ache, nausea) are uncommon. Hypersensitivity reactions of the skin (e.g. exanthema, erythema, pruritus) are rare. Furthermore, allergic reactions like e.g. angioedema, dyspnoea, face oedema may occur. At the first signs of a hypersensitivity reaction Sinupret must not be taken again.

**Dosage and use:**

Adults and adolescents from the age of 12 years: 50 drops or 2 coated tablets thrice daily.

Children of 6 to 11 years: 25 drops or 1 coated tablets thrice daily.

Children of 2 to 5 years: 15 drops thrice daily.

The Sinupret coated tablets is taken with a small quantity of water without chewing.

If symptoms persist for more than 7-14 days or reoccur periodically, consult your doctor.

**Overdose:**

**Peroral administration:**

No case of overdose has been reported.

Treatment of overdose:

In case of overdose, symptomatic treatment should be initiated.

**Interaction with other medications:**

Combining Sinupret with antibacterial agents is allowed, as well as advisable. The interaction with other medications is unknown.

**Pregnancy and lactation period:**

Like all medicinal products Sinupret should be administered during pregnancy and lactation only after strict risk-benefit evaluation by the attending physician. Because Sinupret contains alcohol, drops can only be taken, when it is impossible to take coated tablets.

**Specific instructions:**

The use of Sinupret coated tablets is not recommended in children under 6 years of age, the use of Sinupret oral drops is not recommended in children under 2 years of age.

The medication does not influence the ability to drive a vehicle or operate machinery.

Because Sinupret drops contain alcohol, the solution cannot be administered to patients suffering from alcoholism, even after successful alcohol abuse treatment.

In the case of a liver disease, Sinupret drops shall be administered only after advice from a physician.

Patients suffering from alcoholism, liver diseases or epilepsy should remember that Sinupret contains 19% alcohol (ethanol).

A sole adult dose contains 0.45 g of alcohol, which corresponds to a spoon of wine.

Sinupret coated tablets contain the sugars glucose, lactose, sucrose and sorbitol. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

When using, hold the flask vertically. After a certain time of storage, the liquid may become slightly cloudy or form some sediment. This does not change the effectiveness of the medication.

Protect the coated tablets against moisture.  
Shake the flask of Sinupret drops before use.

**ATC code: R07AX**

**Packaging:**

Oral drops – glass bottle of 100 ml;  
Coated tablets – blister-packs with 25 coated tablets in each;  
packaging – 50 and 100 coated tablets.

**Storage conditions:**

Keep protected from light and store in a dry place at a temperature not higher than 25°C.

**Shelf life:**

2 years for oral drops and 3 years for coated tablets.

3 months after opening the flask.

Do not use the medication after the expiration date indicated on the packaging.

**Dispensing procedure:**

Rx. With medical prescription.

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