



**For registration proposal and translation  
in the Scientific Centre of Drug and Medical Technology  
Expertise of Armenia**

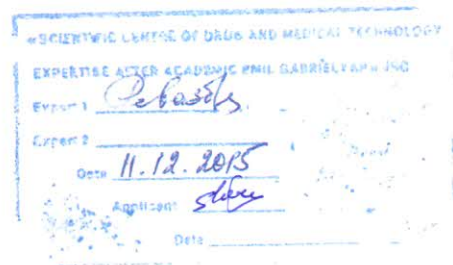
**Package leaflet: Information for the user**

***Sinupret® forte***

***Coated tablets***

Active substances:

- Gentiane radix powdered
- Verbenae herba powdered
- Rumicis herba c powdered
- Sambuci flos powdered
- Primulae flos powdered



For use in adolescents from the age of 12 years and adults

**Read all of this leaflet carefully before you start taking this medicine.**

**This medicine is available with prescription. However, you still need to take Sinupret forte carefully to get the best results from them.**

- Keep this leaflet. You may need to read it again.
- Ask your 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.

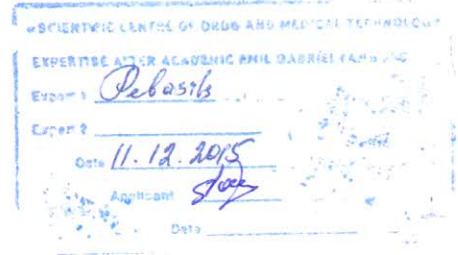
**In this leaflet:**

1. What Sinupret forte are and what they are used for



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2. Before you take Sinupret forte
3. How to take Sinupret forte
4. Possible side effects
5. How to store Sinupret forte
6. Further information



**1. WHAT SINUPRET FORTE ARE AND WHAT THEY ARE USED FOR**

Sinupret forte is a herbal medicine used in acute and chronic inflammations of the paranasal sinuses.

**2. BEFORE YOU TAKE SINUPRET FORTE**

**Do not take Sinupret forte:**

if you are hypersensitive to Gentian root, Vervain herb, Sorrel herb, Elder flowers, Primula flowers or to any of the other ingredients of this medicine (See section 6 FURTHER INFORMATION for other ingredients).

**Take special care with Sinupret forte:**

For complaints lasting longer than 7-14 days or that recur periodically, contact a doctor.

**Children:**

Sinupret forte should not be used in children under 12 years of age.

There are no sufficient investigations to date on the use of Sinupret forte in children under 12 years of age.

**Taking other medicines:**

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

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



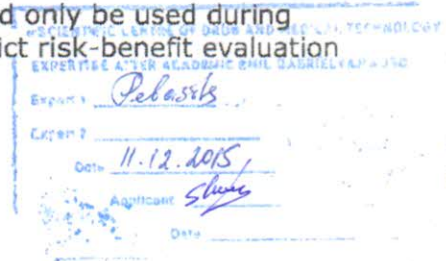
### Pregnancy and breast-feeding:

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

Like all medicines, Sinupret forte should only be used during pregnancy and breast-feeding after strict risk-benefit evaluation by the attending physician.

### Driving and using machines:

No special precautions are required.



### Important information about some of the ingredients of Sinupret forte:

This medicine contains the sugars glucose, lactose, sucrose and sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

## 3. HOW TO TAKE SINUPRET FORTE

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

Unless otherwise prescribed by your doctor, the usual dose is:

Age	Single dose	Total daily dose
Adults and adolescents from 12 years of age	1 coated tablet	3 coated tablets (3 times 1 coated tablet)

### Method of administration:

Swallow Sinupret forte coated tablets 3 times daily (morning, noon, evening) unchewed, with some liquid (e.g. a glass of water). You can take Sinupret forte with meals, with beverages or independently of meals. If you have a sensitive stomach, you should best take Sinupret forte after meals.

### How long should you take Sinupret forte:



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

**If you take more Sinupret forte than you should:**

If you have taken a larger quantity of Sinupret forte than you should have, please notify your doctor. Your doctor can decide whether any other action is necessary. It is possible that the side effects listed below may be more intense.

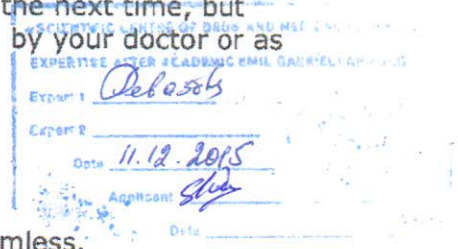
**If you forget to take Sinupret forte:**

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

**If you stop taking Sinupret forte:**

Discontinuing Sinupret forte 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 forte can cause side effects, although not everybody gets them.

The following frequency categories are used for the evaluation of side effects:

<b>Very common:</b>	more than 1 out of 10 persons treated
<b>Common:</b>	1 to 10 out of 100 persons treated
<b>Uncommon:</b>	1 to 10 out of 1,000 persons treated
<b>Rare:</b>	1 to 10 out of 10,000 persons treated
<b>Very rare:</b>	less than 1 out of 10,000 persons treated
<b>Unknown:</b>	evaluation of frequency on basis of available data not possible



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

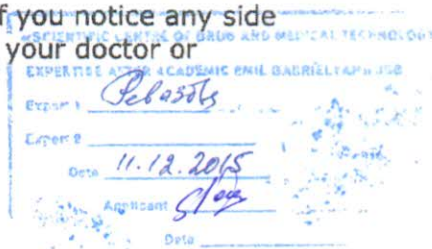
Gastrointestinal disorders (such as stomach ache, nausea) are uncommon.

Hypersensitivity reactions of the skin (skin rash, skin redness, itching) are rare. Furthermore, allergic reactions (swelling of the lips, tongue and throat and/or larynx with narrowing of the airways (angioedema), shortness of breath, swelling of the face) may occur.

At the first sign of a hypersensitivity reaction, Sinupret forte 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.

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.



## 5. HOW TO STORE SINUPRET FORTE

Do not store above 30°C.  
Keep out of the reach and sight of children.

Do not use Sinupret forte after the expiry date which is stated on the carton and the blister. The expiry date refers to the last day of that month.

Sinupret forte coated tablets has a total shelf life of 36 months.

## 6. FURTHER INFORMATION

### What Sinupret forte contains

The active substances are:

Active pharmaceutical ingredients:

1 coated tablet contains powdered:

Verbenae herba 36 mg; Gentiane radix 12 mg; Rumicis herba 36 mg; Sambuci flos 36 mg; Primulae flos 36 mg.



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The other ingredients are:

Calcium carbonate (E 170); chlorophyll powder 25% (E 141); dextrin, eudragit E 12.5; gelatine; glucose syrup; indigo carmine, E 132, aluminium hydroxide; potato starch; lactose monohydrate; maize starch; light magnesium oxide; montan glycol wax; riboflavin (E 101); refined castor oil; sucrose; shellac; highly disperse silicon dioxide; sorbitol; stearic acid; talc; titanium dioxide (E 171).

Note for diabetics:

One coated tablet contains an average of 0.03 carbohydrate exchange units (CEU).

**Pharmacotherapeutic group (ATC-Code)**

R05X

**What Sinupret forte looks like and contents of the pack**

Packs containing 20 (N1) coated tablets, 1 blister containing 20 coated tablets

Packs containing 50 (N2) coated tablets, 2 blister each containing 25 coated tablets

Packs containing 100 (N3) coated tablets, 4 blister each containing 25 coated tablets

Clinic pack containing 500 (10 x 50) coated tablets.

Sinupret forte are green, round, biconvex coated tablets with a smooth surface.

**Dispensing procedure:**

Rx. With medical prescription.



**Pharmaceutical entrepreneur and manufacturer:**

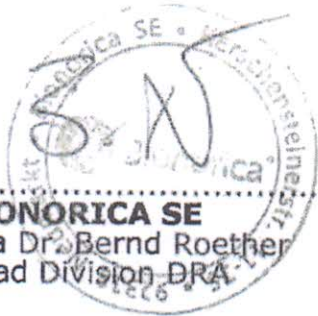
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