

Solpa-Sinus Film-coated tablets
Paracetamol 500mg
Pseudoephedrine hydrochloride 30mg
POWERFUL RELIEF FROM SINUS PAIN & CONGESTION

Please read right through this leaflet before you start using this medicine.

This medicine is available without prescription, but you still need to use SolpaSinus carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- If you have any questions, or there is something you do not understand, ask your pharmacist.

In this leaflet:

1. What SolpaSinus does
2. Check before you take SolpaSinus
3. How to take SolpaSinus
4. Possible side effects
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1. What SolpaSinus does

SolpaSinus is used for the relief of nasal congestion when combined with fever and/or pain such as sore throat, sinus pain or headache in the common cold or flu. The medicine contains two active ingredients. Paracetamol is a painkiller and reduces your temperature when you have a fever. Pseudoephedrine hydrochloride is a decongestant which unblocks your nose and sinuses helping you breathe more easily without drowsiness.

2. Check before you take SolpaSinus

Do not take SolpaSinus:

- If you have ever had an allergic reaction to paracetamol, pseudoephedrine hydrochloride or other sympathomimetics (such as decongestants, appetite suppressants or stimulant drugs called amphetamines), or any of the other ingredients (listed in Section 6).
- If you have high blood pressure, overactive thyroid gland, enlarged prostate, heart problems, glaucoma (excessive pressure inside your eyes).
- If you have kidney problems, unless your doctor tells you to.
- If you have taken monoamine oxidase inhibitors (MAOIs), usually prescribed for depression, in the last two weeks.
- If you are taking the drug moclobemide for depression, beta-blockers for high blood pressure, the antibiotics furazolidone or linezolid, appetite suppressants, or stimulant drugs called amphetamines (sometimes used to treat attention deficit disorders or excessive sleepiness).
- For more than 5 days unless your doctor tells you to.
- If you are under 12 years.
- Do not take with any other paracetamol containing products.

- Do not take with any other flu, cold or decongestant product.

Driving and using machines:

This product can cause dizziness as a side effect which could affect your ability to drive or use machines.

Ask your doctor before you take this medicine:

If you are due to undergo general anaesthesia, or have liver disease, including alcoholic liver disease, diabetes, irregular heart beat or pheochromocytoma (a tumour near the kidney).

Reduction of blood flow to your optic nerve may occur with SolpaSinus. If you develop sudden loss of vision, stop taking SolpaSinus and contact your doctor or seek medical attention immediately. See section 4.

If you are taking other medicines:

Talk to your doctor or pharmacist before taking these tablets if you are taking any prescribed medicines; particularly:

- anticoagulants (used to thin the blood, e.g. warfarin);
- metoclopramide or domperidone (for nausea [feeling sick] or vomiting [being sick]);
- cholestyramine (to lower blood cholesterol);
- medicines for high blood pressure;
- medicines for depression (tricyclic antidepressants);
- sodium bicarbonate (used to treat indigestion and certain kidney conditions).

Pregnancy and breastfeeding:

Do not take SolpaSinus if you are pregnant or breastfeeding.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take SolpaSinus

Take the tablets with a glass of water.

Adults (including the elderly) and children aged 16 and over:

Swallow 2 tablets up to 3 times daily, every 4-6 hours as needed.

Do not take more than 6 tablets (3 doses) in 24 hours.

Children aged 12 to 15 years:

Give 1 tablet every 4-6 hours as needed.

Do not give more than 3 tablets in 24 hours.

Do not take more than every 4 hours.

Do not take for more than 5 days.

Do not take more than the recommended dose.

If you take too many tablets:

Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.

If your symptoms persist, see your doctor or pharmacist.

4. Possible Side Effects

Like all medicines SolpaSinus can have side effects, but not everybody gets them:

Stop taking this medicine and tell your doctor immediately if you experience:

- Sudden severe headache. This is very rare (occurring in fewer than 1 in every 10,000 patients treated).
- Allergic reactions such as skin rash or itching, sometimes with breathing problems (or a hissing sound when you breathe) or swelling of the lips, tongue, throat or face. These reactions are rare (occurring in fewer than 1 in every 1,000 patients treated).
- Breathing problems, especially if you have experienced a similar reaction with aspirin or non-steroidal anti-inflammatories. These are very rare (occurring in fewer than 1 in 10,000 patients treated).
- Reduced blood flow to the optic nerve (Ischaemic optic neuropathy) (frequency Not known).
- Skin rash or peeling, or mouth ulcers. These effects are very rare (occurring in fewer than 1 in 10,000 patients treated).
- Unexplained bruising or bleeding, or infections such as sore throat - this may be a sign of very rare changes in the blood. These occur in fewer than 1 in 10,000 patients treated.
- Difficulty in passing urine. This is uncommon (occurring in fewer than 1 in every 100 patients treated) and is more likely to occur if you have an enlarged prostate gland.

The following side effects may occur. Tell your doctor or pharmacist if you get them.

- Nausea [feeling sick], vomiting [being sick], dry mouth, sleep disturbance, nervousness and dizziness. These are common side effects, (occurring in fewer than 1 in every 10 patients treated).
- Rapid or irregular heart rate, agitation and restlessness. These are uncommon side effects (occurring in fewer than 1 in every 100 patients treated).
- High blood pressure and hallucinations are rare side effects, (occurring in fewer than 1 in every 1,000 patients treated).

This product may have side effects that you would not notice yourself. These include changes in some liver test results.

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 HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to Store SolpaSinus

Keep out of the reach and sight of children.

Do not take the medicine after the "EXP" date shown on the blister and outer carton.

Do not use the medicine if you notice the tablets are soft.

Do not store above 25°C.

6. Further Information

Active ingredients: Each tablet contains Paracetamol 500mg and Pseudoephedrine Hydrochloride 30mg.

Other ingredients: Cellulose microcrystalline (E460), silica, colloidal anhydrous (E551), stearic acid (E570), magnesium stearate (E572), starch pregelatinised, povidone, crospovidone, croscarmellose sodium (E468), hypromellose (E464), macrogol, carnuba wax (E903), indigo carmine (E132).

What SolpaSinus looks like and contents of the pack

The tablets are blue and white and marked with a figure “2” in a circle.

Packs contain 2, 5, 6, 10, 12, 16, 18, 24, 30 or 32 tablets.

Marketing Authorisation Holder and Manufacturer

The marketing authorisation holder is Chefaro Ireland DAC, The Sharp Building, Hogan Place, Dublin 2 Ireland and all enquiries should be sent to this address.

The manufacturer is Famar A.V.E. Anthoussa Plant, Anthoussa Avenue 7, Anthoussa Attiki, 15349, Greece.

This leaflet was last revised in April 2021.

Solpa-Sinus is registered trademark of Omega Pharma Corporate.

This medicinal product is authorised in the Member States of the EEA under the following names:

Ireland	Solpa-Sinus Film-coated tablets Paracetamol 500mg Pseudoephedrine Hydrochloride 30mg
Portugal	Panadol Sinus 500 mg + 30 mg Tablets
Sweden	Panodil Duo filmdragerade tabletter
UK	Panadol Cold and Sinus 500 mg/ 30 mg Film-coated Tablets

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