Package leaflet: Information for the user

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

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

What is in this leaflet

1. What this medicine is and what it is used for

Solpa-Sinus 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 in adults and in .

This medicine contains the active substances Paracetamol 500mg, which is a painkiller and reduces your temperature when you have a fever and Pseudoephedrine hydrochloride 30mg, which is a decongestant which unblocks your nose and sinuses helping you breathe more easily without drowsiness.

2. What you need to know before you take this medicine

Do not take Solpa-Sinus:

- if you are allergic to paracetamol, pseudoephedrine hydrochloride or other sympathomimetics (such as decongestants, appetite suppressants or stimulant drugs called amphetamines), or any of the other ingredients of this medicine (listed in Section 6);
- if you have very high blood pressure (severe hypertension) or hypertension not controlled by your medication
- if you have severe acute (sudden) or chronic (long-term) kidney disease or kidney failure
- If you have overactive thyroid gland, enlarged prostate, heart problems,glaucoma (excessive pressure inside your eyes);
- if you have diabetes;
- if you have phaeochromocytoma (a tumour near the kidney);
- 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);
- with any other paracetamol containing products;
- with any other flu, cold or decongestant product;
- for more than 5 days unless your doctor tells you to;
- if you are under 12 years old

Warning and precautions

Cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) have been reported following use of medicines containing pseudoephedrine. PRES and RCVS are rare conditions that can involve reduced blood supply to the brain. Stop using <Product Name> immediately and seek immediate medical assistance if you develop symptoms that may be signs of PRES or RCVS (see section 4 "Possible side effects" for symptoms).

Talk to your doctor or pharmacist before taking this medicine:
- if you are due to undergo general anaesthesia;
- if you have irregular heart beat;
- if you have chronic alcoholism;
- if you have kidney or liver problems;
- if you have Gilbert's Syndrome (familial non-haemolytic jaundice);
- if you are taking other medicines that can effect the liver;
- if you are dehydrated;
- if you have had poor diet such that the diet causes health problems;
- if you weigh less than 50kg;
- if you are elderly;
- if you have glucose-6-phosphate dehydrogenase deficiency;
- if you have haemolytic anaemia;
- if you have frequent or daily headaches;
- if you have asthma and sensitivity to acetylsalicylic acid.

They may reduce the dose or increase the time interval between doses of your medicine.

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

Other medicines and Solpa-Sinus
Tell your doctor or pharmacist if you are taking, have recently taken or might take use any other 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);
- probenecid (used to treat gout and reduce uric acid);
- chrolamphenicol (antibiotic);
- anticonvulsants or other medicines used to treat epilepsy (such as barbiturates);
- oral contraceptive steroids.
- flucloxacillin (antiobitic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.

Pregnancy and breastfeeding:

Do not take Solpa-Sinus if you are pregnant or breastfeeding.
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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

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

3. How to take this medicine

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Adults (including the elderly) and children aged 16 and over:
- 2 tablets up to 3 times daily, every 4-6 hours as needed.
- Do not take more than 8 tablets in 24 hours

Elderly patients, especially those who are frail or immobile, may require a reduced dose or frequency of dosing.

Children aged 12 to 15 years:
- 1 tablet every 4-6 hours as needed.
- Do not give more than 3 tablets in 24 hours.

For oral use. The tablet should be taken with water

Do not take more frequently than every 4 hours.
Do not take for more than 3 days.
Do not take more than the recommended daily dose.

If you take more Solpa-Sinus that you should
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. Liver damage may become apparent 12 to 48 hours after ingestion. Cardiac arrhythmias and pancreatitis have been reported.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines Solpa-Sinus can have side effects, but not everybody gets them:

- serious conditions affecting blood vessels in the brain known as posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) (frequency not known)

Stop using Solpa-Sinus immediately and seek urgent medical attention if you develop symptoms, that may be signs of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS). These include:

• severe headache with a sudden onset

• feeling sick

• vomiting

• confusion

• seizures changes in vision

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 and pain 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;
- Small bumps on your skin full of fluid or pus (pustules);
- Diarrhoea with blood and mucus, abdominal pain and fever.

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

If you do get any side effects, even those not mentioned in this leaflet, tell your doctor or pharmacist.

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 this medicine

Keep out of the reach and sight of children.

Do not take this medicine after the expiry date which is stated on the blister and outer carton. The expiry date refers to the last day of that month.

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

Do not store above 25°C.

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

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What this medicine contains
The active substances are
- Paracetamol 500mg and Pseudoephedrine Hydrochloride 30mg.
- Other ingredients are 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 this medicine 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.

Not all pack sizes may be marketed

Marketing Authorisation Holder
The marketing authorisation holder is Chefaro Ireland DAC, The Sharp Building, Hogan Place, Dublin 2 Ireland
All enquiries should be sent to above address.

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

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