



# Panadol Sinus Caplets

## PRODUCT INFORMATION



### Each caplet contains:

- Paracetamol 500 mg
- Pseudoephedrine Hydrochloride 30 mg

**Other Ingredients:** Talc-Purified, Povidone, Starch-Pregelatinised maize, Sodium benzoate, Starch-Maize, Stearic acid

### What is Panadol Sinus and what is it used for?

Panadol Sinus is a white caplet which contains Paracetamol which is an Analgesic and Antipyretic and Pseudoephedrine which is a nasal decongestant.

For the short time relief of sinusitis symptoms including sinus headache, sinus pain, and nasal congestion.

Also it is used for relief of fever and body aches.

### How to take Panadol Sinus?

For Oral administration only.

Adults (including the elderly) and children aged 12 years and over:

- 1 to 2 caplets to be taken orally every 4 to 6 hours but do not take more than 8 caplets in 24 hours.
- Consult your doctor if symptoms persist for more than 7 days.
- Do not take more frequently than every 4 hours.
- Do not use in children under the age of 12 years.

### Before You Take Panadol Sinus

#### a. Do not use Panadol Sinus if:

- You have previous history of hypersensitivity to paracetamol, pseudoephedrine, or any of the other ingredients of Panadol Sinus.
- You have severe hypertension or severe coronary artery disease.
- You are taking other sympathomimetics (such as decongestants, appetite suppressants, and amphetamine-like psychostimulants).
- You are taking or have taken in the past 2 weeks drug named MonoAmine Oxidase inhibitors (MAOIs) as it may lead to hypertensive crisis.
- You have severe renal impairment.

#### b. Take special care with Panadol Sinus if:

You should consult your doctor before taking this product if:

- You have liver impairment or mild to moderate kidney impairment.
- You have cardiovascular disease, arrhythmias, hypertension, hyperthyroidism, prostatic enlargement, diabetes, glaucoma or phaeochromocytoma.
- If you are taking beta-blockers or other antihypertensives.

You have glutathione depleted states such as sepsis or you have a severe infection as the use of Paracetamol may increase the risk of metabolic acidosis. Signs of metabolic acidosis include:

- deep, rapid, difficult breathing
- Feeling sick (nausea), being sick (vomiting)
- Loss of appetite

Contact a doctor immediately if you get a combination of these symptoms.

There have been reports of ischaemic colitis with Pseudoephedrine. Pseudoephedrine should be discontinued immediately and medical advice sought if sudden abdominal pain, rectal bleeding or other symptoms of ischaemic colitis develop.

There have been rare cases of posterior reversible encephalopathy (PRES)/reversible cerebral vasoconstriction syndrome (RCVS) reported with sympathomimetic drugs, including pseudoephedrine. Symptoms reported included sudden onset of severe headache, nausea, vomiting, and visual disturbances. Most cases improved or resolved within a few days following appropriate treatment. Pseudoephedrine should be discontinued, and medical advice sought immediately, if signs/symptoms of PRES/RCVS develop.

- If you experience sudden severe headache.

\* This product contains 0.6 mg Sodium benzoate per tablet to be taken into consideration by patients on controlled Sodium diet.

\* Do not exceed the stated dose.

\* This product contains Paracetamol and Pseudoephedrine. Do not use with other products containing paracetamol or decongestants products.

\* Keep medication out of sight and reach of children.

\* Please see your doctor if your symptoms persist, do not improve, worsen or new symptoms occur.

### C. Taking other medications:

- The liver toxic effects of Panadol Sinus may be increased by the use of alcohol. Avoid drinking alcohol with this medicine.
- The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular daily use of paracetamol-containing products with increased risk of bleeding; occasional doses have no significant effect.

- Concomitant administration of pseudoephedrine hydrochloride-containing products and MAOIs (or within two weeks of stopping of MAOI) may lead to hypertensive crisis.

- Concomitant use of this medication with sympathomimetic agents (such as decongestants, appetite suppressants and amphetamine-like psychostimulants) which interfere with the catabolism of sympathomimetic amines, may occasionally cause a rise in blood pressure.

- Pseudoephedrine-containing products may antagonise the effect of certain classes of antihypertensives

### d. Pregnancy and lactation:

This product should not be used during pregnancy or while breastfeeding without consulting your doctor.

Safe use of Pseudoephedrine in pregnancy has not been established despite widespread use over many years.

Caution should be exercised by balancing the potential benefit of treatment to the mother against any possible hazards to the developing foetus.

Pseudoephedrine is excreted in breast milk in small amounts but the effect of this on breast fed infants is unknown.

### e. Driving and using machines:

This product can cause drowsiness, dizziness, or blurred vision. You should not drive or operate machinery until you are sure you are not affected.

### Possible Adverse Reactions

Stop using this product and consult your doctor immediately if:

#### Paracetamol:

- You experience allergic reactions such as skin rash or itching, sometimes with breathing problems or swelling of the lips, tongue, throat or face.
- You experience a skin rash or peeling, or mouth ulcers.
- In very rare cases you may experience angioedema or Stevens Johnson syndrome.
- You have previously experienced breathing problems or bronchospasm with aspirin or non-steroidal anti-inflammatories, and experience a similar reaction with this product.
- You experienced liver dysfunction related symptoms or signs.
- You experience unexplained bruising or bleeding.

#### Pseudoephedrine HCl:

- Nervousness, difficulty sleeping, dizziness, dry mouth, nausea and vomiting, may occasionally occur. Rare reactions may include hallucinations.
- Tachycardia, palpitations, increased blood pressure (increase in systolic blood pressure has been observed, at the therapeutic doses the effects of Pseudoephedrine on blood pressure are not clinically significant), rash, allergic dermatitis (such as bronchospasm and angioedema).
- Uncommon reactions such as agitation, restlessness, dysuria, urinary retention (most likely to occur in those with bladder outlet obstruction such as prostatic hypertrophy).

### Overdose

Seek medical advice immediately in the event of overdose even if symptoms of overdose are not present.

#### Paracetamol:

Paracetamol overdose may cause liver failure. Immediate medical management is required in the event of overdose, even if symptoms of overdose are not present.

- In massive over dosage exceeding 10g of paracetamol may cause liver damage. Early symptoms may include pallor, nausea, vomiting, excessive sweating and general malaise.
- Clinical and laboratory evidence of liver damage may not be apparent until 48 to 72 hours past ingestion.

Overdose should be promptly treated by gastric lavage followed by intravenous N-acetylcysteine or methionine without waiting for the results of plasma paracetamol levels.

- Additional antidote therapy is normally considered in light of further plasma paracetamol levels and the time elapsed since ingestion. In all cases of suspected overdose, prompt medical attention is critical for adults as well as for children, even if you do not notice any signs or symptoms.

#### Pseudoephedrine:

Pseudoephedrine overdose may result in symptoms due to central nervous system and cardiovascular stimulation.

e.g. excitement, restlessness, hallucinations, hypertension and arrhythmias. In severe cases, psychosis convulsions, coma and hypertensive crisis may occur. Serum Potassium levels may be low due to extracellular shifts in Potassium.

Treatment should consist of standard supportive measures.

Beta blockers should reverse the cardiovascular complications and the hypokalemia.

### How to store Panadol Sinus?

Store below 30° C.

Pack size: 24's ( 12's Blisters x 2 )

### THIS IS A MEDICINE

• **Medicine is a product which affects your health, and its consumption contrary to instructions is dangerous for you.**

• **Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicine.**

• **The doctor and pharmacist are experts in the use of medicines, its benefits and risks.**

• **Do not by yourself interrupt the period of treatment prescribe for you.**

• **Do not repeat the same prescription without consulting your doctor.**

**KEEP MEDICINE OUT OF REACH OF CHILDREN**

**Council of Arab Health Ministers  
Union of Arab Pharmacists**

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For GlaxoSmithKline Consumer Healthcare Australia Pty Ltd, Australia.

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