

# Panadol Sinus Relief PE Caplets

## PRODUCT INFORMATION

### Description

Each tablet contains: Paracetamol BP, 500 mg  
Phenylephrine hydrochloride BP,  
5 mg

### Other Ingredients:

Maize starch, Pregelatinised starch, Povidone, Potassium sorbate, Sodium Lauryl Sulfate, Stearic acid, Purified Talc, Microcrystalline Cellulose.

### Indications:

Panadol Sinus Relief PE is recommended for:

- Short term symptomatic relief of cold and flu symptoms including headache, sore throat, nasal congestion, sinusitis and yellow/green nasal discharge, body aches and pains, and fever.
- Short term relief of sinusitis symptoms including sinus headache, sinus pain and nasal congestion.

### Dosage and administration:

- For oral administration.
- If symptoms persist, consult a doctor.
- Do not exceed the stated dose.
- Do not take more frequently than every 4 hours.
- This Product contains Paracetamol. Do not use with other paracetamol-containing products, decongestants, or cough and cold medicines.

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

- Take two caplets with water every 4-6 hours as required.
- Do not take more than 8 caplets per day.
- Do not use for more than 7 days without medical advice.

### Children under 12 years:

- Not recommended for children under the age of 12 years, except on medical advice.

### Children under 6 years:

- This medication should not be used for treatment of cold and flu for children below 6 years (containing phenylephrine).

### Contraindications:

Panadol Sinus Relief PE is contraindicated in patients:

- With known or previous history of hypersensitivity to paracetamol, phenylephrine, or any of the excipients (ingredient in the product).
- Who are taking, or have taken, within the last two weeks, monoamine oxidase inhibitors (MAOIs).

### Warnings and Precautions

Please see your doctor if your symptoms do not improve or persist or get worse or new symptoms occur because these could be signs of a serious condition.

Panadol Sinus Relief PE may increase the effects of alcohol therefore, alcohol should be avoided.

Medical advice should be sought before taking Panadol Sinus Relief PE if you are:

- Patients who have been diagnosed with liver or kidney impairment.
- You have high blood pressure, heart disease or blood vessel disease as occlusive vascular disease such as Raynaud's phenomenon (which may appear as pain in the fingers or toes in response to cold or stress).
- You have diabetes.
- You have hyperthyroidism (overactive thyroid).
- You have angle closure glaucoma (excessive pressure inside your eyes)
- You have pheochromocytoma (a tumour near the kidney)
- You have enlargement or problem of the prostate gland or difficulty urinating

Use with caution if you are:

- Taking beta-blockers and other antihypertensive drugs.
- Taking tricyclic antidepressants.

Panadol Sinus Relief PE should not be used by:

- Patients taking other sympathomimetics (such as decongestants, appetite suppressants and amphetamine-like psychostimulants).

If symptoms persist, consult a doctor.

Keep this and all medication out of sight and reach of children.

**Ability to perform tasks that require judgment, motor or cognitive skills:** should not drive or operate machinery if affected by dizziness.

### Pregnancy & Lactation

This product should not be used during pregnancy or breast feeding without medical advice.

This Product should not be used whilst breast feeding without medical advice. Phenylephrine may be excreted in breast milk.

### Adverse Reactions

These reactions are rare.

Stop using this product and consult your doctor immediately if:

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- 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.
- You have previously experienced breathing problems with aspirin or non-steroidal anti-inflammatory, and experience a similar reaction with this product.
- You experience unexplained bruising or bleeding.
- You experience loss of vision, which may be due to abnormally high blood pressure in the eye. This is more likely to occur in those with glaucoma.
- You experience difficulty in passing water. This is more likely to occur in men with an enlarged prostate gland.
- You experience and unusually fast or irregular heartbeat.

### Paracetamol

If you are in doubt of any symptoms or sign please consult your physician.

Adverse event frequencies have been estimated to be very rare. These adverse events include: thrombocytopenia, anaphylaxis, cutaneous hypersensitivity reactions including skin rashes, angiodema, and stevens johnson syndrome, bronchospasm in patients sensitive to aspirin and other NSAIDs and hepatic dysfunction.

### Phenylephrine

Adverse events have been observed in clinical trials with phenylephrine: nervousness, headache, dizziness, insomnia (difficult to sleep), increased blood pressure, nausea, vomiting. Other Adverse events have been reported during post marketing use as mydriasis, acute angle closure glaucoma (most likely to occur in those with closed angle glaucoma), tachycardia, palpitations, allergic reactions (e.g. rash, urticaria, and allergic dermatitis), dysuria, and urinary retention (This is most likely to occur in those with bladder outlet obstruction, such as prostatic hypertrophy).

### Drug Interactions

#### Paracetamol

The liver toxic effects of Panadol Sinus Relief PE may be increased by the use of alcohol.

The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular daily use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.

#### Phenylephrine

Medical consultation should be sought before taking Panadol Sinus Relief PE and caution if you are:

- Patient taking beta-adrenergic blocking agents and other antihypertensive. Phenylephrine may reduce the efficacy of beta blocking drugs and antihypertensive drugs. The risk of hypertension and other cardiovascular side effects may be increased.
- Patient taking tricyclic antidepressants, which may increase the risk of cardiovascular side effects with phenylephrine.
- Patients taking other sympathomimetics (such as decongestants, appetite suppressants). Concomitant use of phenylephrine with sympathomimetic amines can increase the risk of cardiovascular side effects.
- Patients taking Digoxin and cardiac glycosides. Concomitant use of phenylephrine with digoxin or cardiac glycosides may increase the risk of irregular heartbeat or heart attack.
- Patient taking Monoamine oxidase inhibitors. Concomitant use of phenylephrine with other sympathomimetic amines can increase the risk of cardiovascular and hypertensive side effects.

### Overdose

#### 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 that may cause liver failure. Early symptoms may include pallor, nausea, vomiting, (diaphoresis) 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. General supportive measures must be available. 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.

#### Phenylephrine

Overdose of Phenylephrine is likely to result in effects similar to those listed under adverse reactions. Additional symptoms may include irritability, restlessness, hypertension, and possibly reflex bradycardia. In severe cases confusion, hallucination, seizures and arrhythmias may occur. Treatment should be as clinically appropriate. Severe hypertension may need to be treated with an alpha blocking drug such as phentolamine.

### Pharmaceutical Storage

Store below 30° C. Store in well sealed container.

### 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 doctors' 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