



Panadol Cold & Flu Tablet

Patient information leaflet



Description

Each Tablet contains:

Paracetamol 500 mg
Pseudoephedrine Hydrochloride 50 mg
Chlorpheniramine Maleate 2 mg

Other Ingredients: Silicon dioxide, stearic acid, sodium benzoate, povidone, pregelatinized starch, maize starch, talc.

What is Panadol Cold & Flu and what is it used for?

Panadol Cold & Flu is a White capsule-shaped tablet that contains Paracetamol which is Analgesic and Antipyretic, Pseudoephedrine which is an indirect acting sympathomimetic amine and Chlorpheniramine Maleate which is a potent antihistaminic.

It is used for the relief of the symptoms of common cold and influenza such as: fever, muscle ache, nasal congestion, sinus congestion, headache and sinus pain, sneezing, itchy and watery eyes.

How to Take Panadol Cold & Flu?

For Oral Administration Only.

Adults and Children 12 years and over:

2 capsules taken with water every 6 hours as necessary, maximum 8 capsules within 24 hours.

Use in adults: Paracetamol should not be taken for more than a few days at a time except on medical advice.

Use in children aged 12 to 17 years: Paracetamol should not be taken for more than 48 hours except on medical advice.

Do not use in children below 12 years of age.

Do not exceed the stated dose or frequency of dosing.

Minimum dosage interval: 6 hours.

Seek medical advice if symptoms persist for more than 7 days.

Before you take Panadol Cold & Flu

a. Do not take Panadol Cold & Flu:

- If you have known previous history of allergy to paracetamol, pseudoephedrine hydrochloride, Chlorpheniramine maleate, other antihistamines or any of the other ingredients of Panadol Cold & Flu.
- If you have severe hypertension or severe coronary artery disease.
- If you are receiving other sympathomimetics (such as decongestants, appetite suppressants and amphetamine like psychostimulants).
- If you are taking or have taken in the past two weeks, drug called Monoamine Oxidase Inhibitors (MAOIs).
- If you have stenosing peptic ulcer
- If you have symptomatic prostatic hypertrophy
- If you have bladder neck obstruction
- If you have pyloroduodenal obstruction
- If you have severe renal impairment
- If you have narrow-angle glaucoma
- If you are lactating women

b. Take special care with Panadol Cold & Flu in case of:

Check with your doctor before use if:

- You have mild to moderate kidney impairment or hepatic impairment.

- You have cardiovascular disease, coronary heart disease, ischaemic heart disease arrhythmias, hypertension, hyperthyroidism, prostatic hypertrophy, diabetes, pheochromocytoma, epilepsy, bronchitis, bronchiectasis and bronchial asthma.

- You have raised intra-ocular pressure including glaucoma.

- You have glaucoma depleted states such as sepsis or you have a severe infection as the use of Paracetamol may increase the risk of metabolic acidosis.

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.

- Chlorpheniramine may increase the effects of alcohol and therefore consumption of alcohol should be avoided.
- Concurrent use with drugs which cause sedation, such as anxiolytics and hypnotics may cause an increase in sedative effects.
- You are taking beta-blockers or other anti-hypertensives because of the pseudoephedrine content.
- Children and the elderly are more likely to experience neurological anticholinergic effects and paradoxical excitation (e.g. increased energy, restlessness, nervousness).

- Stop using this product and seek immediate medical attention if you experience sudden severe headache.

- This product contains paracetamol, Pseudoephedrine and Chlorpheniramine. Do not use with other products containing paracetamol, decongestants or antihistamines or other flu, cough and cold preparations.

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

- If symptoms persist, get worse or new symptoms appear please consult your doctor.

- Medical advice should be sought if the symptoms persist, or is accompanied by a high fever, skin rash or persistent headache.

- Do not exceed the stated dose or frequency of dosing.

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

c. Possible drug interactions:

- The anticholinergic 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.
- Paracetamol absorption is increased by substances that increase gastric emptying, e.g. metoprololamide
- Paracetamol absorption is decreased by substances that decrease gastric emptying, e.g. propantheline, antidepressants with anticholinergic properties, and narcotic analgesics
- Paracetamol may increase chloramphenicol concentrations
- The risk of paracetamol toxicity may be increased in patients receiving other potentially hepatotoxic drugs or drugs that induce liver microsomal enzymes such as alcohol and anticonvulsant agents
- Paracetamol excretion may be affected and plasma concentrations altered when given with probenecid
- Cimetidine reduces the absorption of paracetamol if given within 1 hour of paracetamol.
- Concomitant administration of pseudoephedrine hydrochloride-containing products and antidepressant medication e.g. tricyclic antidepressants and (MAOIs) may cause a serious increase in blood pressure or hypertensive crisis.
- Concurrent use of this medicine with sympathomimetic agents (such as decongestants, appetite suppressants and amphetamine-like psychostimulants) which interfere with the catabolism of sympathomimetic amines, may occasionally cause rise in blood pressure.
- Pseudoephedrine may antagonise the effect of certain classes of antihypertensives
- urinary alkalines enhance elimination of pseudoephedrine. urinary alkalines decrease elimination of pseudoephedrine
- Concurrent use of Chlorpheniramine and (CNS) depressants (alcohol, sedatives, opioid analgesics, hypnotics) - may cause an increase in sedation effects.
- Monoamine oxidase inhibitors (MAOI) and tricyclic antidepressants (TCA) - may prolong and intensify the anticholinergic and CNS depressive effects.
- Chlorpheniramine when taken with monoamine oxidase inhibitors (MAOI) may cause a decrease in blood pressure.
- Chlorpheniramine inhibits phenytoin metabolism and can lead to phenytoin toxicity.
- The liver toxic effects of Panadol Cold & Flu may be increased by the use of alcohol. **Avoid drinking alcohol with this medicine.**

d. Pregnancy and lactation:

This product should not be used during pregnancy or whilst breastfeeding without medical advice. Safe use of pseudoephedrine in pregnancy has not been established despite widespread use over many years. Caution should therefore be exercised by balancing the potential benefit of treatment to the mother against any possible risk to the foetus.

There are no adequate data from the use of Chlorpheniramine maleate in pregnant women.

The potential risk for humans is unknown. Use during the third trimester may result in reactions in the newborn or premature neonates.

e. Driving and using machines:

The anticholinergic properties of Chlorpheniramine in this product may cause drowsiness, dizziness, or blurred vision and psychomotor impairment. You should not drive or operate machinery if you are affected.

Possible Adverse events

Stop using this product and consult your doctor immediately if:

Paracetamol:

- In very rare cases: thrombocytopenia, Anaphylaxis, (cutaneous hypersensitivity reactions including among others, skin rashes, angioedema, Stevens Johnson syndrome and Toxic Epidermal Necrolysis, Bronchospasm in patients sensitive to aspirin and other NSAIDs, Hepatic dysfunction.

Pseudoephedrine HCl:

- Nervousness, insomnia, dizziness, restlessness, tremors, dry mouth, nausea and vomiting, these are common.
- Rare reactions may include Hallucinations, Tachycardia, arrhythmia or 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 (variety of allergic skin reactions, with or without systemic features such as bronchospasm and angioedema have been reported following the use of pseudoephedrine).
- Uncommon reactions such as agitation, restlessness, dysuria, urinary retention (most likely to occur in those with bladder outlet obstruction, such as prostatic hypertrophy).

Chlorpheniramine Maleate:

- Sedation, somnolence are very common.
- Disturbance in attention, abnormal coordination, dizziness, headache, Nausea, dry mouth, Fatigue, Anxiety, hallucinations, appetite stimulation, muscle dyskinesias, and activation of epileptogenic foci, Dryness of the eyes and nose, blurred vision, urinary hesitancy and retention, constipation and tachycardia these reactions are common.
- Other reactions may include: Allergic reactions, angioedema, anaphylactic reactions, Anorexia, Confusion*, excitation*, irritability*, nightmares*, Hypotension, Thickening of bronchial secretions, Vomiting, abdominal pain, diarrhoea, dyspepsia, Exfoliative dermatitis, rash, urticaria, photosensitivity, Muscle twitching, muscle weakness, Urinary retention, Chest tightness.
- Children and the elderly are more susceptible to neurological anticholinergic effects and paradoxical excitation (e.g. increased energy, restlessness, nervousness).

Overdose:

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

Paracetamol:

Experience following overdose with paracetamol indicates that the clinical signs of liver injury occur usually after 24 to 48 hours and have peaked after 4 to 6 days. Paracetamol overdose may cause liver failure, which may require liver transplant or lead to death and rarely, acute renal tubular necrosis. Acute pancreatitis has been observed, usually with hepatic dysfunction and liver toxicity

Immediate medical management is required in the event of overdose, even if symptoms of overdose are not present.

If overdose is confirmed or suspected, seek immediate advice from your doctor

This should happen even in patients without symptoms or signs of overdose due to the risk of delayed liver damage. Administration of N-acetylcysteine or methionine may be required.

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 hypokalaemia.

Chlorpheniramine:

Overdose is likely to result in effects similar to those listed under adverse reactions. Additional symptoms may include: paradoxical excitation, toxic psychosis, convulsions, apnoea, dystonic reactions and cardiovascular collapse including arrhythmias. Treatment should be supportive and directed towards specific symptoms. Convulsions and marked CNS stimulation should be treated with parenteral diazepam.

How to Store Panadol Cold & Flu?

Store below 30° C.

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

Do not use this medicine after the expiry date which is stated on the carton, Blister. The expiry date refers to the last day of that month.

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 prescribed 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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