

Panadol Cold & Flu caplets

PRODUCT INFORMATION

Night

Description

Each tablet contains: Paracetamol 500 mg
Pseudoephedrine Hydrochloride 30 mg
Chlorpheniramine Maleate 2 mg

Pharmacology

Paracetamol is a clinically proven analgesic and antipyretic. Pseudoephedrine is a sympathomimetic agent, for symptomatic relief from nasal congestion. Chlorpheniramine maleate is an antihistamine.

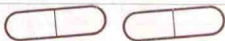
Indications

Panadol Cold & Flu caplets are indicated for the relief of symptoms of the common cold and influenza such as: fever, nasal congestion, sinus congestion, headache and sinus pain, sneezing, itchy and watery eyes.

Dosage and Administration

Panadol Cold and Flu caplets are suitable for adults and children of 12 years of age and over.

Adults and children of 12 years and over:
Two caplets up to four times a day.



If necessary the dose may be repeated every four to six hours but do not take more than four doses (8 caplets) in 24 hours.

Contraindications

Panadol Cold and Flu caplets are contra-indicated in patients with known hypersensitivity to paracetamol, pseudoephedrine hydrochloride or chlorpheniramine maleate or related compounds. Not to be used by patients taking monoamine oxidase inhibitor antidepressants or within 2 weeks of stopping such treatment.

Precautions

Keep out of reach of children.

This preparation contains paracetamol. Do not exceed the stated dose. Do not take other paracetamol containing medications, nasal decongestants or antihistamines at the same time as Panadol Cold and Flu caplets. Panadol Cold & Flu caplets should be administered with caution to patients with hepatic or renal dysfunction, severe hypertension, cardiac or peripheral vascular disease, hyperthyroidism, or on antihypertensive or antidepressant therapy.

Pseudoephedrine should be given with care to patients with diabetes mellitus, closed-angle glaucoma or prostate enlargement. Anginal pain may be precipitated in angina pectoris.

Antihistamines should be used with caution in conditions such as epilepsy, prostatic enlargement, urinary retention, glaucoma, severe cardiovascular disorders or pyloroduodenal obstruction.

Do not take this product for pain for more than 10 days or for fever for more than 3 days unless directed by a doctor. If pain persists or gets worse, if new symptoms occur, or if redness and swelling is present, consult a doctor because these could be signs of a serious condition. If nervousness, dizziness or insomnia occur, or if a sore throat is severe and persists for more than 2 days and is accompanied by fever, headache, rash, nausea or vomiting, consult a doctor promptly.

Use in Pregnancy and Lactation

Although there are no known risks associated with the use of these active ingredients during pregnancy, as with all medicines, medical advice should be sought before using this product. Panadol Cold & Flu should not be used during breast feeding as it may be risky associated with the use of antihistamines in infants.

Use in children

Do not give to children below 12 years of age.

Driving and Operating Machinery

Since Panadol Cold & Flu caplets contain an antihistamine, sedation may occur impairing the ability to drive or operate machinery.

Side effects

Paracetamol: When taken in recommended doses, paracetamol is usually free from side effects. However skin reactions such as urticaria have been reported rarely.

Pseudoephedrine: May occasionally cause anxiety, tremor, dizziness, cardiovascular effects including tachycardia and hypertension, insomnia and urinary retention. A fixed erythematous drug eruption has been reported rarely.

Chlorpheniramine: The antihistamine may cause sedation, gastrointestinal disturbances and antimuscarinic effects.

Drug Interactions

Paracetamol: Panadol Cold & Flu caplets may interact with anticoagulant agents on prothrombin time.

The liver effects of Panadol Cold & Flu caplets may be increased by the use of alcohol and the concomitant use of certain drugs which enhance the metabolism of paracetamol in the liver (e. barbiturates, tricyclic antidepressants).

Coadministration of pseudoephedrine and MAOIs may lead to hypertensive crisis. This effect may persist for up to 2 weeks after discontinuation of MAOIs.

Enhanced sedative effects of chlorpheniramine can occur with simultaneous administration of alcohol, anxiolytics and hypnotics. Tricyclic antidepressants and antimuscarinics can increase antimuscarinic side effects.

Overdose

In massive paracetamol overdosage, Panadol Cold & Flu caplets may cause liver damage. Early symptoms may include pallor, nausea, vomiting, (diaphoresis) and general malaise.

Clinical and laboratory evidence of liver damage may not be apparent for 48 to 72 hours post-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 overdose is likely to result in effects similar to those listed as adverse effects, and may also produce excess sympathetic stimulation. 7-8 caplets has been shown to cause hypertension in normotensive subjects. Treatment of pseudoephedrine overdose is mainly symptomatic. Measures should be taken to support respiration and control hypertension. Convulsions should be supported with an anticonvulsant if required. Elimination of pseudoephedrine can be accelerated by acidification of the urine.

Antihistamine overdosage may cause sedation and central nervous system depression.

THIS IS A MEDICINE

- Medicines are products that affect your health, and failure to follow the instructions may be dangerous for you.
- Follow your doctor's advice carefully, the method of use, and the instructions of the pharmacist who sold you the medicine.
- Your doctor and pharmacist are expert in the use of medicines, and their benefits and risks.
- Do not stop your course of treatment early unless advised to do so by your doctor or pharmacist.
- Do not repeat your prescription without consulting your doctor.

KEEP MEDICINES OUT OF REACH OF CHILDREN

Council of Arab Health Ministers
Union of Arab Pharmacists

Pharmaceutical precautions:

Store below 25° C. Store in a well sealed container.



GlaxoSmithKline

Manufactured by GlaxoSmithKline Australia Pty Limited,
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Product information Prepared April 2004. Version 4.0.

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