

Panadol Cold+Flu All in One - Tablets

PRODUCT INFORMATION

Description

Each tablet of Panadol Cold+Flu All in One contains:

- Paracetamol 250 mg
- Phenylephrine Hydrochloride 5 mg
- Guafenesin 100 mg

Excipient

Lactose, Microcrystalline Cellulose, Maize Starch Pregelatinised, Purified Talc, Maize Starch, Stearic Acid, Colloidal Anhydrous Silica, Povidone, Potassium Sorbate, Water Purified, Opady II OY-LS-28913 White

Indications

Panadol Cold+Flu All in One tablets are indicated for the short term symptomatic relief of colds, chills and influenza including chesty coughs.

Dosage

Adults and children 12 years and over: Take 2 tablets. Repeat every 4 hours as necessary.

Do not take more than 8 tablets in 24 hours.

Not to be given to children under 12 years except on medical advice.



- If symptoms persist, consult a doctor.
- Do not exceed the stated dose.
- Minimum dosing interval: 4 hours.
- Should not be used with other paracetamol-containing products, decongestants, or cough and cold medicines.

Contraindications

This product is contraindicated in patients:

- With known hypersensitivity to Paracetamol, Guafenesin, Phenylephrine, or any of the excipients.
- With hepatic or severe renal impairment, hypertension, hyperthyroidism, diabetes, heart disease or those taking tricyclic antidepressants, monoamine oxidase inhibitors or beta-blocking drugs.
- This medication should not be used for the treatment of cough and cold symptoms in children under 6 years of age.

Warnings and Precautions

- Medical advice should be sought before taking this product in patients with: Hypertension, Cardiovascular disease, Diabetes, Hyperthyroidism, Angle closure glaucoma, Phaeochromocytoma, Enlargement of the prostate gland, Obstructive vascular disease (e.g. Reynaud's Phenomenon) and Liver and kidney impairment.
- Use with caution in patients taking: Beta-blockers and other antihypertensive drugs and tricyclic antidepressants.
- This product should not be used by patients taking other sympathomimetics (such as decongestants, appetite suppressants and amphetamine-like psychostimulants).
- Contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactose deficiency or glucose-galactose malabsorption should not take this medicine.
- If symptoms persist, consult a doctor.
- Keep out of sight and reach from Children.

Use in Pregnancy and Lactation

Pregnancy

This product should not be used during pregnancy without medical advice. The safety of Guafenesin during pregnancy has not been established.

Lactation

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

Adverse Reactions

Paracetamol

Adverse events from historical clinical trial data are both infrequent and from small patient exposure. The frequency of these reactions is unknown but considered likely to be very rare (<1/10,000). Thrombocytopenia, Anaphylaxis, Cutaneous Hypersensitivity reactions including skin rashes, angioedema, and Stevens Johnson syndrome, Bronchospasm in patients sensitive to Aspirin and other NSAIDs, Hepatic dysfunction.

Phenylephrine

The following adverse events have been observed in clinical trials with phenylephrine and may therefore represent the most commonly occurring adverse events. The frequency of these reactions is unknown but considered likely to be rare (≥1/10,000, <1/1000). Nervousness, Headache, Dizziness, Insomnia, Increased blood pressure, Nausea, Vomiting, Mydriasis, Acute Angle Closure Glaucoma (most likely to occur in those with closed angle glaucoma), Tachycardia, Piloerection, Allergic reactions (e.g. rash, urticaria, allergic dermatitis), Dysuria, Urinary Retention (this is most likely to occur in those with bladder outlet obstruction such as prostatic hypertrophy).

Guafenesin

Adverse events from historical clinical trial data are both infrequent and from small patient exposure. The frequency of these events is unknown but considered likely to be rare (≥1/10,000, <1/1000). Allergic reactions, Angioedema, Anaphylactic reactions, Dyspnoea (dyspnoea has been reported in association with other symptoms of hypersensitivity), Nausea, Vomiting, Abdominal discomfort, Rash and Urticaria.

Drug Interaction

- The anticoagulant effect of Warfarin and other Coumatins may be enhanced by prolonged regular daily use of Paracetamol with increased risk of bleeding; occasional doses have no significant effect.
- Phenylephrine should be used with caution in combination with the following drugs as interactions have been reported:

Monoamine oxidase inhibitors:	Hypertensive interactions occur between sympathomimetic amines such as phenylephrine and monoamine oxidase.
Sympathomimetic amines:	Concomitant use of phenylephrine with other sympathomimetic amines can increase the risk of cardiovascular side effects.
Beta-blockers, and other antihypertensives:	Phenylephrine may reduce the efficacy of beta-blocking drugs and antihypertensive drugs. The risk of hypertension and other cardiovascular side effects may be increased.
Tricyclic antidepressants:	May increase the risk of cardiovascular side effects with Phenylephrine.
Drugs and cardiac glycosides:	Increase the risk of irregular heartbeat or heart attack.

- No significant interactions with other drugs have been noted for Guafenesin.

Overdose

Paracetamol

Symptoms and signs: overdose may cause liver failure.

Treatment: Immediate medical management is required in the event of overdose, even if symptoms of overdose are not present. Administration of N-acetylcysteine or methionine may be required.

Phenylephrine

Symptoms and signs: Phenylephrine over dosage is likely to result in effects similar to those listed under adverse reactions. Additional symptoms may include irritability, restlessness, hypertension and possibly reflex brachycardia. In severe cases confusion, hallucinations, 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.

Guafenesin

Symptom and Signs: Very large doses of Guafenesin cause nausea and vomiting.

Treatment: Vomiting would be treated by fluid replacement and monitoring of electrolytes if indicated.

Pharmaceutical Storage

Store below 30° C.

THIS IS A MEDICAMENT

- Medicament 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 MEDICAMENT OUT OF REACH OF CHILDREN

Council of Arab Health Ministers
Union of Arab Pharmacists



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