DECONGEX COLD

Syrup

Composition
Each 5 ml contains Paracetamol 160 mg, Chlorpheniramine maleate 1 mg and Pseudoephedrine hydrochloride 15 mg.

Action
Decongestant, analgesic, antipyretic, and antihistaminic properties.

Indications
For the relief of symptoms of nasal stuffiness, runny nose, sneezing, minor aches and pains, headaches and fever due to the common cold, hay fever or other nasal allergies.

Contraindications
- Do not use this product if you are allergic to any of the ingredients.
- Do not use this product if you are being treated with monoamine-oxidase inhibitors, or within two weeks of stopping treatment with these medications.
- Paracetamol should not be used in patients with severe liver disease.
- Pseudoephedrine should not be used in patients suffering from any of the following: heart disease (especially coronary insufficiency or arrhythmias), high blood pressure (hypertension), an overactive thyroid gland (hyperthyroidism), tumor of the adrenal gland (phaeochromocytoma) and raised intra-ocular pressure (closed-angle glaucoma).
- Do not take this product during pregnancy or whilst breast-feeding.
- Pseudoephedrine should be avoided in patients receiving chloroform, cyclopropane, halothane or other halogenated anaesthetics.

Warnings
Taking more than the recommended dose may cause severe liver damage.
Patients suffering from liver or kidney disease should take paracetamol only if instructed to do so by the doctor.
This medicine may lead to drowsiness and impaired concentration, which may be aggravated by simultaneous intake of alcohol or other agents that slow down the nervous system activity. Patients should be warned against taking charge of vehicles or machinery or performing potentially dangerous tasks where loss of concentration may lead to accidents.
Consult your doctor if no relief is obtained with the recommended dosage.
Do not use continuously for longer than 10 days without consulting your doctor.

Adverse Reactions and Precautions
Paracetamol may cause allergic reactions and skin rash. The rash usually appears as red areas or allergic wheals, and may be accompanied by fever and involvement of the mucous membranes.
The use of paracetamol has been associated with the occurrence of neutropenia, pancytopenia and leucopenia.

Pseudoephedrine may cause giddiness, headache, nausea, and vomiting, sweating, thirst. rapid or irregular heart beat (tachycardia, ventricular arrhythmia), pain in front of the heart (precordial pain), palpitations, raised blood pressure (hypertension), difficulty in urination, muscular weakness, tremors, anxiety, restlessness and inability to sleep. Tolerance with dependence may occur after continued use.

The effects of pseudoephedrine are lessened by medicines containing guanethidine, reserpine, and methyldopa and may be diminished or enhanced by tricyclic antidepressants. It may increase the possibility of irregular heartbeat in patients taking digitalis.

Chlorpheniramine may cause sedation, lassitude, dizziness, in coordination; central nervous system stimulation (insomnia, nervousness, euphoria, irritability, tremors, nightmares, hallucinations and

convulsions) especially in children; antimuscarinic effects (e.g. dry mouth, thickened respiratory-tract secretions and tightness of the chest, blurred vision, urinary difficulty and retention, disturbances affecting the stomach and intestines resulting in constipation, and increased gastric reflux); vomiting, diarrhoea, epigastric pain, nausea and anorexia; headache; ringing in the ears; paresthesias (tingling sensation); and hypotension (low blood pressure). In high doses, slight slowing of the heart beat may occur, followed by an increased heart rate and irregular heartbeats.

Hypersensitivity reactions, particularly of the skin, and cross-sensitivity to related medicines may occur; photosensitivity (sensitivity to sunlight) and blood disorders have been reported.

Chlorpheniramine should be given with care to patients with raised pressure in the eye (glaucoma), difficulty in passing urine, enlargement of the prostate gland, pyloroduodenal obstruction, patients with epilepsy or severe cardiovascular disorders, unless it is prescribed by your doctor.

Other central nervous system depressants, such as alcohol, barbiturates, hypnotics, opioid analgesics, anxiolytic sedatives, and neuroleptics, if taken together will increase the chance of sedation.

Be careful when taking medicines containing, tricyclic antidepressants, or atropine together.
Elderly patients are more susceptible to many of the adverse effects including antimuscarinic effects, sedation and lowering of blood pressure.
The warning signs of damage caused by ototoxic medicines may be masked by chlorpheniramine.
Chlorpheniramine may interfere with the results of skin tests and should be stopped several days before such tests.

Dosage and Administration

Not recommended for children under the age of two years.
Children aged 2 –5 years: One 5 ml teaspoonful.
Children aged 6 –11 years: Two 5 mL teaspoonfuls.
Doses may be repeated every 4 –6 hours as needed. Do not exceed 4 doses in 24 hours.

Over Dosage

Paracetamol

Initial symptoms in the first 24 hours are nausea, vomiting, anorexia, and abdominal pain and these may persist for a week or more.

Liver injury may become apparent from 12 to 48 hours after ingestion and may manifest by metabolic acidosis, abnormalities of glucose metabolism, elevation of serum transaminase and lactic dehydrogenase activity, increased serum bilirubin concentration and prolongation of prothrombin time. The liver damage may progress to encephalopathy, coma, and death. Cerebral edema, cardiac arrhythmias, and nonspecific myocardial depression have also occurred. Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage.
Prompt treatment is essential. Any patient who has ingested about 7.5 g of paracetamol in the preceding 4 hours should undergo gastric lavage. Specific therapy with an antidote such as acetylcysteine or methionine may be necessary. If decided upon acetylcysteine should be administered intravenously as soon as possible. Acetylcysteine is effective if administered within 8 hours of over dosage.

Intravenously: An initial dose of 150 mg/kg in 200 ml glucose injection, given intravenously over 15 minutes, followed by an intravenous infusion of 50 mg/kg in 500 ml of glucose injection over the next 4 hours and then 100 mg/kg in 1000 ml over the next 16 hours. The volume of intravenous fluids should be modified for children.
Oraly: 140 mg/kg as a 5% solution initially, followed by a 70 mg/kg solution every 4 hours for 17 doses.

Pseudoephedrine

Symptoms from pseudoephedrine overdose consist most often of mild anxiety, increased rate of heart beat and/or mild high blood pressure. Symptoms usually appear within 4 to 8 hours of over dosage being taken.

Chlorpheniramine
Over Dosage may result in antimuscarinic, extrapyramidal, gastro-intestinal, and central nervous system effects. In children and infants, central nervous system stimulation predominates over depression causing ataxia, excitement, tremors, psychoses, hallucinations, and convulsions; hyperpyrexia may also occur. Deepening coma and cardio respiratory collapse may occur.

In adults, central nervous system depression is more common with drowsiness, coma, and convulsions progressing to respiratory failure or possibly cardiovascular collapse. In severe over dosage, the stomach should be emptied. Convulsions may be controlled with diazepam. Other treatment is supportive and related to symptoms.

Presentation
Bottle of 100 ml