

XTPARA COLD DS

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only

Abbreviated Prescribing information for XTPARA COLD DS [Paracetamol, Phenylephrine HCl,

Chlorpheniramine Maleate, Ammonium Chloride, Sodium Citrate & Menthol Suspension]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: *Paracetamol* – Analgesic: Primarily works through the CNS by inhibiting prostaglandin synthesis, reducing pain sensitivity. Antipyretic: Acts on the hypothalamus to decrease fever by reducing prostaglandin production and promoting heat loss mechanisms like sweating. *Phenylephrine* – Sympathomimetic Nasal Decongestant: Reduces nasal congestion by stimulating α -adrenergic receptors, causing vasoconstriction and reducing swelling of the nasal mucosa. *Chlorpheniramine Maleate* – Antihistamine: Blocks histamine H1 receptors, preventing histamine induced dilation of capillaries and edema in the respiratory mucosa. *Sodium citrate* – Mucus Liquefier: Acts as a mucus liquefier by increasing the volume of respiratory tract secretions, aiding their removal through ciliary action and coughing. *Ammonium Chloride* – Expectorant: Stimulates the bronchial mucosa, enhancing fluid production to loosen phlegm and facilitate expectoration. *Menthol* – Demulcent: Soothes the throat by reducing irritation of mucous membranes and calming the effects of mechanical, chemical or bacterial irritants.

INDICATION: For symptomatic treatment of common cold and flu-like syndrome.

DOSAGE AND ADMINISTRATION: *Posology:* Children between 6 to 12 years of age: 5 ml to be administered upto 4 times daily. Adults and adolescents: 10 ml to be administered up to 4 times daily for oral administration. Shake suspension well before use. *Method of administration:* For oral administration. Shake suspension well before use.

CONTRAINDICATION: a) Known hypersensitivity to paracetamol, phenylephrine, chlorpheniramine maleate, sodium citrate, ammonium chloride, menthol or to any other component of the formulation. b) In patients with hypersensitivity to any of its ingredients, those who have used monoamine oxidase inhibitors (MAOIs) in the last 14 days. c) In patients who are currently receiving other sympathomimetic drugs. d) Cardiovascular disorders. e) In patients with peripheral vascular insufficiency f) In patients with hyperthyroidism. g) In patients with glaucoma. h) In patients with prostate problem. i) Pheochromocytoma. j) In patients having aluminium toxicity, untreated Addison's disease, heart disease, hyperkalemia, renal impairment, dehydration (due to its sodium citrate content). k) In patients with hepatic or renal impairment (due to its ammonium salt).

WARNINGS & PRECAUTIONS: *Paracetamol*- Overdose can cause hepatotoxicity, especially in those with liver impairment or chronic alcohol use. *Phenylephrine*- With caution in patients with cardiovascular, thyroid or prostate issues and avoided with other sympathomimetics due to potential CNS effects like insomnia and tremors. *Chlorpheniramine Maleate* – Drowsiness and CNS effects and used cautiously in patients with peptic ulcers, urinary bladder obstruction, epilepsy, raised intraocular pressure, severe hypertension or bronchial disorders. *Ammonium Chloride*- Monitor for ammonia toxicity and use cautiously in patients with pulmonary insufficiency, cardiac edema, or hepatic dysfunction, avoiding use in primary respiratory acidosis. *Menthol*- hypersensitivity reactions and should be kept away from infants and children to prevent apnoea or collapse.

DRUG INTERACTIONS: *Paracetamol:* Cholestyramine, Metoclopramide and Domperidone, Warfarin, Chloramphenicol, Alcohol, Anticonvulsants, and Isoniazid. *Phenylephrine:* MAO inhibitors, Sympathomimetic Amines, Beta-Blockers and Other Antihypertensive Drugs (including Debrisoquine, Guanethidine, Reserpine, and Methyl dopa), Tricyclic Antidepressants (Amitriptyline), Ergot Alkaloids (Ergotamine and Methylsergide), and Digoxin and Cardiac Glycosides. *Chlorpheniramine Maleate:* Alcohol, Hypnotics, Anxiolytics, Sedatives, Opioid Analgesics, and Neuroleptics, Phenytoin, MAO Inhibitors and Tricyclic Antidepressants. *Sodium Citrate:* Acidic Drugs, Aluminium-Containing Compounds, Lithium or Tetracyclines (e.g., Doxycycline), Anorexiant (e.g., Phentermine) or Sympathomimetics (e.g., Pseudoephedrine). *Ammonium Chloride:* Basic Drugs (Amphetamines, Quinidine), Potassium-Sparing Diuretics and Acidic Drugs. *Menthol:* Drugs Metabolised by CYP3A4.

ADVERSE REACTIONS: *Paracetamol*- Skin rash, fixed drug eruption, thrombocytopenic purpura, methaemoglobinemia, agranulocytosis, constipation, dyspepsia, dry mouth, and heartburn. *Phenylephrine*- Elevated blood pressure, headache, vomiting, palpitations, tachycardia, reflex bradycardia, tingling and cool skin. *Chlorpheniramine Maleate*- sedation (ranging from drowsiness to deep sleep), inability to concentrate, dizziness, muscular weakness, tinnitus, depression, irritability, and nightmares. In children, paradoxical excitation and in the elderly, confusional psychosis may occur and anorexia. Other adverse effects include urinary retention, blurred vision, arrhythmias, hypotension, chest tightness, jaundice, haemolytic anaemia, blood dyscrasias, urticaria, exfoliative dermatitis, and photosensitivity reactions. *Ammonium Chloride*- nausea, diarrhea, and abdominal pain. *Menthol*- vertigo, ataxia, and coma.

MARKETED BY:



Torrent Pharmaceuticals Limited.

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(Additional information is available on request)