

# Dexta Cold-C<sup>®</sup>

## Syrup

**Category:** Analgesic, antihistaminic (H<sub>1</sub> - receptor), antitussive, decongestant.

**Composition:** Each 5 ml of syrup contains 160 mg acetaminophen, 1mg chlorpheniramine maleate, 5 mg dextromethorphan HBr and 2.5 mg phenylephrine HCl.

**Mechanism of action:**

Acetaminophen may act predominantly by inhibiting prostaglandin synthesis in the central nervous system (CNS) and, to a lesser extent, through a peripheral action by blocking pain impulse generation.

Acetaminophen probably produces antipyresis by acting centrally on the hypothalamic heat-regulating center to produce peripheral vasodilation resulting in increased blood flow through the skin, sweating and heat loss.

Chlorpheniramine maleate is an alkylamine type antihistamine that is used in the treatment of allergy act by competing with histamine for H<sub>1</sub>-receptor sites on effector cells. Also, the anticholinergic actions of it provide a drying effect on the nasal mucosa.

Dextromethorphan HBr acts by a direct action on the cough center in the medulla of the brain. Phenylephrine hydrochloride is a sympathomimetic with mainly direct effects on adrenergic receptors.

**Pharmacokinetics:**

**Acetaminophen:**

Absorption: Oral – Rapid and almost complete.

Biotransformation: 90 to 95% of a dose is metabolized in the liver.

Half-life: 1 to 4 hours.

Time to peak concentration: 0.5 to 2 hours.

Duration of action: 3 to 4 hours.

Elimination: Renal

**Chlorpheniramine:**

Absorption: well absorbed.

Protein binding: 72%

Time to peak concentration: 2 to 6 hours

Duration of action: 4 to 8 hours.

**Dextromethorphan:**

Biotransformation: Hepatic.

Onset of action: One-half hour.

Duration of action: Up to 6 hours.

Elimination: Primarily renal.

**Phenylephrine:**

Phenylephrine has low oral bioavailability owing to irregular absorption and first-pass metabolism by monoamine oxidase in the gut and liver.

**Indications:**

Dexta Cold-C<sup>®</sup> is indicated for the temporary relief of nasal and sinus congestion and headaches, pains, nonproductive cough and general discomfort due to colds, flu, or allergies. The antihistamine in these combinations may provide added relief of nasal congestion, rhinorrhea, and sneezing.

**Contraindications:**

Dexta Cold-C<sup>®</sup> syrup is contraindicated in patients with a history of hypersensitivity to any of its ingredients.

**Drug interactions:**

Anticholinergic or other medications with anticholinergic activity, ototoxic medications, medicine for high blood pressure or depression or CNS depressants or stimulants, fluoxetine, amiodarone, quinidine and monoamine oxidase (MAO) inhibitors including furazolidone, phenelzine, procarbazine, selegiline and tranylcypromine.

**Precautions:**

**Pregnancy** – Concern for the fetus and / or newborn infant only with high doses and long-term therapy.

**Breast** - feeding - Antihistamines may cause excitement or irritability in nursing infant; high risk for infants from sympathomimetic amines.

**Use in children** - Increased susceptibility to anticholinergic effects of antihistamines and to vasopressor effects of sympathomimetic amines; hyperexcitability (paradoxical reaction) may occur.

**Use in the elderly**—anticholinergic and CNS stimulant effects more likely to occur.

**Risk - benefit should be considered when the following medical problems exist:**

Alcoholism, cardiovascular disease, diabetes, hypertension, hyperthyroidism, bladder neck obstruction, prostatic hypertrophy, urinary retention, glaucoma, asthma, chronic bronchitis, productive cough, emphysema, hepatic and renal function impairment, respiratory depression.

**Side/Adverse effects:**

**Those indicating need for medical attention**

Nausea or vomiting; stomach pain ; bloody or black tarry stools; changes in urine or problems with urination; skin rash, hives or itching; sore throat and fever; swelling of face, feet or lower legs, tightness in chest; unusual bleeding or bruising; unusual tiredness or weakness; vomiting of blood or material that looks like coffee grounds; weight gain (unusual); yellow eyes or skin.

**Those indicating need for medical attention only if they continue or are bothersome**

Drowsiness; thickening of mucus; blurred vision; confusion; difficult or painful urination; dizziness; dryness of mouth, nose or throat ; headache; loss of appetite; nightmares; pounding heartbeat; ringing or buzzing in ears; stomach upset; unusual excitement, nervousness, restlessness or irritability.

**Administration and dosage:**

- Children 6-12 years : 5 to 10 ml of syrup every 4-6 hours.

- Children 2-6 years : Use and dose must be determined by doctor.

**Packaging:**

Dexta Cold-C<sup>®</sup> syrup is available as clear solution in 60 ml bottles.



Manufactured by Amin

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