

Dextromethorphan Hydrobromide and Chlorpheniramine Maleate Cough Syrup

COREX[®] Dx



1. GENERIC NAME

Dextromethorphan Hydrobromide and Chlorpheniramine Maleate Cough Syrup.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Corex Dx Cough Syrup contains Chlorpheniramine Maleate and Dextromethorphan Hydrobromide as active ingredients.

Each 5 ml of Corex Dx syrup contains:

Dextromethorphan Hydrobromide	I.P. 10.0 mg
Chlorpheniramine Maleate	I.P. 4.0 mg

List of Excipients

Purified water I.P., Refined Sugar I.P., sodium benzoate I.P., saccharin sodium I.P., sodium citrate I.P., Sorbitol Solution (70%, non-crystallising) I.P., citric acid monohydrate I.P., tartaric acid I.P., color sunset yellow FCF, color carmoisine, nutmeg oil, flavour pineapple PC, menthol I.P.

3. DOSAGE FORM AND STRENGTH

Syrup.

Strength: Refer to Section 2

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Corex Dx syrup is indicated for the treatment of dry, irritating, disturbing cough in allergic or infective conditions of the respiratory passage, e.g., sinusitis, hay fever, pharyngitis, acute bronchitis, tuberculosis, and tropical eosinophilia.

4.2 Posology and Method of Administration

Corex Dx syrup is usually given 4 times a day in the following doses:

Adults: 1 teaspoonful (5 ml)

Children: 6-12 years: 1/2 teaspoonful (2.5 ml)

2-6 years: 1/4 teaspoonful (1.25 ml)

4.3 Contraindications

Hypersensitivity to any of the ingredients.

Taking a prescription containing monoamine oxidase inhibitor (MAOI). However, can be taken 14 days after stopping the MAOI drug.

Do not use in children under 2 years of age.

4.4 Special Warnings and Special Precautions for Use

While treating cough as a symptom, it is important to make every effort to determine and treat appropriately the underlying cause such as a specific infection.

Corex Dx should be prescribed with caution and prior consultation, for the patients having history of breathing problems or chronic lung disease (such as chronic bronchitis, asthma or emphysema); glaucoma; trouble urinating due to an enlarged prostate gland (prostate hypertrophy).

Please discontinue Corex Dx and consult a doctor or healthcare professional if cough lasts more than 10 days, with repeated episodes, or is accompanied by fever, rash, or persistent headaches. These could be signs of a serious condition.

Do not exceed recommended dosage.

4.5 Drug Interactions

Concomitant use of Corex Dx along with monoamine oxidase inhibitor (MAOI) should be avoided as this may increase side effects. Administration may commence following 14 days washout period subsequent to discontinuation of MAOI therapy. Due to additive pharmacologic effect, the concomitant use of sedatives and tranquilizers should be avoided as this may increase drowsiness. Avoid use of alcohol as alcohol as this may increase drowsiness.

Dextromethorphan is primarily metabolized by the cytochrome P450 isoform CYP2D6; the possibility of interactions with inhibitors of this enzyme, including amiodarone, fluoxetine, haloperidol, paroxetine, propafenone, quinidine, and thioridazine should be borne in mind.

4.6 Use in Special population

Pregnancy or Lactation

If pregnant or breast-feeding, ask a health professional before use.

4.7 Effects on Ability to Drive and Use Machines

Patients whose work or occupation involves driving vehicles or handling machinery should be cautioned not to drive a vehicle or handle a machine if they feel drowsy while taking

Corex Dx syrup. The preparation may cause drowsiness, and patients should not drive or operate machinery requiring alertness and it is contraindicated in chronic obstructive pulmonary disease.

4.8. Undesirable Effects

The following side effect have been associated with the use of **Dextromethorphan** and is listed under their corresponding body system organ class:

Immune system disorders: Hypersensitivity

The following side effects have been associated with the use of **Chlorpheniramine** and are listed under their corresponding body system organ class:

Blood and lymphatic system: Agranulocytosis, hemolytic anemia, hypoplastic anemia, thrombocytopenia

Cardiac disorders: Bradycardia, extrasystoles, palpitations, tachycardia

Eye disorders: Vision blurred, visual disturbance

Gastrointestinal disorders: Constipation, diarrhea, dry mouth, nausea, vomiting

General disorders and administration site conditions: Fatigue, malaise

Immune system disorders: Anaphylactic shock, hypersensitivity

Nervous system disorders: Coordination abnormal, dizziness, headache, sedation, somnolence

Psychiatric disorders: Confusional state, euphoric mood, excitability, irritability, nervousness, restlessness

Renal and urinary disorders: Dysuria, urinary retention

Respiratory, thoracic and mediastinal disorders: Dry throat, nasal dryness

Skin and subcutaneous tissue disorders: Drug eruption, photosensitivity reaction, rash, urticaria

4.9. Overdose

In case of accidental overdose, discontinue use and seek professional assistance immediately.

The following signs and symptoms may be associated with an overdose of Dextromethorphan:

Gastrointestinal disorders: Nausea, vomiting

Nervous system disorders: Depressed level of consciousness, dizziness, dysarthria, nystagmus, somnolence

Psychiatric disorders: Excitability, confusional state, psychotic disorder

Respiratory, thoracic and mediastinal disorders: Respiratory depression

The following signs and symptoms have been observed in patients who received an overdose of Chlorpheniramine:

Eye disorders: Vision blurred

Gastrointestinal disorders: Dry mouth, abdominal discomfort

General disorders and administration site conditions: Fatigue, hyperpyrexia, hyperthermia

Investigations: Heart rate abnormal

Nervous system disorders: Ataxia, depressed level of consciousness, coma, convulsion, dizziness, somnolence, lethargy, sedation

Psychiatric disorders: Anxiety, agitation, delirium, excitability, hallucination, insomnia, nervousness, psychotic disorder

Respiratory, thoracic and mediastinal disorders: Apnea, dyspnea, dry throat, nasal dryness, respiratory arrest, respiratory failure

Vascular disorders: Circulatory collapse, flushing, hypotension, pallor

5. PHARMACOLOGICAL PROPERTIES

5.1 Mechanism of Action

Corex DX syrup combines dextromethorphan hydrobromide (a cough suppressant) and chlorpheniramine maleate (an antihistamine) to treat dry coughs. It works by suppressing the cough reflex in the brain's medulla and blocking histamine receptors to reduce allergy-related irritation, providing relief from throat irritation, sneezing, and runny nose.

Dextromethorphan Hydrobromide (Antitussive): Acts centrally on the cough center in the medulla oblongata to elevate the threshold for coughing, reducing the intensity of cough bouts. It acts as a sigma-1 receptor agonist and NMDA receptor antagonist.

Chlorpheniramine Maleate (Antihistamine): Blocks H1 histamine receptors, which reduces the allergic response (sneezing, runny nose) and prevents histamine-induced irritation of the respiratory mucosa.

5.2 Pharmacodynamic Properties

Chlorpheniramine Maleate, an alkylamine derivative, is H1 blocking antihistaminic. The drugs belonging to this group are not so prone to produce drowsiness and are among the most suitable agents for day time use; but again a significant proportion of patients do experience this effect. It relieves histamine-induced allergic edema of respiratory mucosa.

Dextromethorphan acts centrally on cough center in medulla to elevate the threshold for coughing. This reduces excessive frequency and intensity of cough bouts, which allows the patient to rest or sleep. Its antitussive potency is nearly equal to that of codeine. It has no analgesic or addictive properties.

5.3 Pharmacokinetic Properties

Chlorpheniramine Maleate is absorbed relatively slowly from the gastrointestinal tract; peak plasma concentrations occurring about 2.5 to 6 hours after administration by mouth. Chlorpheniramine appears to undergo considerable first-pass metabolism.

Chlorpheniramine is widely distributed in the body, including passage into the CNS. Chlorpheniramine maleate is extensively metabolized. Unchanged drug and metabolites are excreted primarily in the urine. Duration of action is about 4 to 6 hours. Values ranging from 2 to 43 hours have been reported for half-life. More rapid and extensive absorption, faster clearance, and a shorter half-life have been reported in children.

Dextromethorphan is rapidly absorbed from the gastrointestinal tract. The onset of antitussive action occurs in 15 to 30 minutes after administration and duration is about 6 hours. It is metabolized in the liver and excreted in the urine as unchanged dextromethorphan and demethylated metabolites including dextrophan which has some cough suppressant activity.

6. DESCRIPTION

Bright reddish orange, clear syrupy liquid, free from foreign contaminants.

7. PHARMACEUTICAL PARTICULARS

7.1 Incompatibilities

Not known.

7.2 Shelf life

24 months from the date of manufacture.

7.3 Packaging Information

Bottles of 50 and 100 ml

Amber PET bottles

Aluminium ROPP cap with PVC lined cork wad

7.4 Storage and handling instruction

Store at a temperature not exceeding 30°C. Replace cap securely.

Keep out of reach of children.

8. DETAILS OF MANUFACTURER

Manufactured by:

Pfizer Limited,

Plot No. 47B/2,

Street No.4,I.D.A.,Phase-I

Cherlapally, Hyderabad

Or

Pfizer Limited,
Plot no. 1802-1805, G.I.D.C., Phase III,
VAPI, Dist. Valsad,
Gujarat - 396 195

Or

Pfizer Limited, Khata No. 845/713 and 1108/970/1
34th KM, Tumakuru Road,
T - Begur, Nelamangala,
Bengaluru Rural - 562 123

Or

Pfizer Limited
Plot No. 9/2, IDA Uppal,
Hyderabad

Marketed in India by:

CIPLA LTD, Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel,
Mumbai - 400 013, INDIA

9. DETAILS OF PERMISSION OR LICENSE NO. WITH DATE:

Mfg. Lic. No. *: 45/RR/AP/2007/F/R(L) dated 23-Apr-2008

Mfg. Lic No. *: G/25A/3864-A dated 24-Nov-2016

Mfg. Lic. No. *: KTK/25A/719/2011 dated 22-Apr-2008

Mfg. Lic. No. *: 38/RR/AP/2010/F/R(L) dated 14-Feb-2025

(*The manufacturing license is renewed every 5 years as per Indian regulations).

10. DATE OF REVISION:

February 2026