COREX® Dx Cough Syrup

(Chlorpheniramine Maleate and Dextromethorphan Hydrobromide)

1. NAME OF MEDICINAL PRODUCT

Corex Dx 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:

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

3. PHARMACEUTICAL FORM

Syrup.

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.

Ask a doctor before use if you have breathing problems or chronic lung disease (such as chronic bronchitis, asthma or emphysema); glaucoma; trouble urinating due to an enlarged prostate gland (prostate hypertrophy).

Stop use and ask a doctor or healthcare professional if cough lasts more than 10 days, comes back, or is accompanied by fever, rash, or persistent headaches. These could be signs of a serious condition.

Do not exceed recommended dosage.

4.5 Interactions with Other Medicaments and Other Forms of Interaction

Do not take this product if you are now taking a prescription containing monoamine oxidase inhibitor (MAOI). However can be taken 14 days after stopping the MAOI drug. Ask a doctor (or pharmacist) before use if you are taking sedatives or tranquilizers. Sedatives and tranquilizers may increase drowsiness. Avoid alcohol as alcohol may increase drowsiness.

Dextromethorphan is primarily metabolized by the cytochrome P450 isoform CYPP2D6; 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 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.

4.8. Undesirable Effects

Dextromethorphan:

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

5.0 PHARMACOLOGICAL PROPERTIES

5.1 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.

5.2 Pharmacokinetic Properties

Chlorpheniramine Maleate is absorbed relatively slowly from the gastro-intestinal 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 in to 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 gastro-intestinal 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 dextrorphan which has some cough suppressant activity.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Purified water IP, sucrose (sugar crystals) IP, sodium benzoate IP, saccharin sodium IP, sodium citrate IP, sorbitol solution IP, citric acid monohydrate IP, tartaric acid IP, color sunset yellow, color carmoisine, nutmeg oil, flavour pineapple PC, menthol IP.

6.2 Incompatibilities

Not known.

6.3 Shelf life

24 months from the date of manufacture.

6.4 Special Precautions for Storage

No special precautions for storage.

Keep out of reach of children.

6.5 Nature and Contents of Container

Bottles of 50 and 100 ml
Amber PET bottles
Aluminium ROPP cap with PVC lined cork wad

6.6 Instructions for Handling

None.

References:

1. Reynolds JEF (ed). Martindale The Extra Pharmacopoeia 1999; 32nd edition, London: Royal Pharmaceutical Society; p 399, 404-05, 1056-57.

2. Physicians' Desk Reference 1999; 53rd edition, Montvale, NJ: Medical Economic Company; p 1694-95, 2634-35.