



# Dorenta<sup>®</sup>

Diphenhydramine Hydrochloride Film Coated Tablet and Syrup

## DESCRIPTION

**Dorenta<sup>®</sup>** is a preparation of diphenhydramine hydrochloride. It is a well absorbed antihistamine and widely distributed throughout the body, including CNS. It is principally used for the treatment of rhinitis, urticaria and other allergic conditions.

## INDICATIONS

**Dorenta<sup>®</sup>** is indicated for the treatment of allergic diseases such as hay fever, allergic rhinitis, urticaria, angioedema, atopic dermatitis, contact dermatitis, gastrointestinal allergy, pruritus, physical allergies, reaction to injection of contrast media, reaction to therapeutic preparation and allergic transfusion reactions; also postoperative nausea and vomiting and motion sickness. It is also used for the treatment of certain forms of parkinsonism and certain allergic conjunctivitis. Sometimes it may use as a night time sleep aid and for the short-term management of insomnia.

## DOSAGE AND ADMINISTRATION

### • Antihistamine and antitussive:

#### **Tablet:**

**Adults:** 25 mg to 50 mg 3 to 4 times daily.

**Children (10 years or over):** 25 mg 3 or 4 times daily or as directed by the physician.

#### **Syrup:**

**Children under 2 years** : 2.5 mL every 4 to 6 hours.

**Children 2 to under 6 years** : 5 mL every 4 to 6 hours.

**Children 6 to 12 years** : 10-20 mL every 4 to 6 hours.

**Adults and children ≥ 12 years** : 10-20 mL every 4 to 6 hours.

### • Sleep aid:

**Adults and children over 12 years:** 50 mg at bedtime.

## USE IN PREGNANCY AND LACTATION

Safety for use in pregnancy and lactation has not been established. Its use therefore in such patients should involve consideration of expected benefits and possible risks.

## CONTRAINDICATIONS

**Dorenta<sup>®</sup>** is contraindicated for the premature or newborn infants. Hypersensitivity to any of the component of this drug. Asthma attack, narrow angle glaucoma, prostatic hypertrophy, stenosing peptic ulcer, pyloroduodenal obstructions, bladder neck obstruction, patients receiving antidepressant therapy.

## SIDE-EFFECTS

Side-effects include drowsiness, dizziness and dryness of mouth, nausea and vomiting. Other infrequently reported effects are vertigo, palpitation, blurring of vision, headache, restlessness, insomnia and thickening of bronchial secretions. Allergic reactions, diarrhoea, vomiting and excitation may also occur.

## OVERDOSE

Antihistamine over dosage reactions may vary from central nervous system depression to stimulation. Stimulation is particularly likely in children. Atropine-like signs and symptoms such as dryness of mouth, fixed and dilated pupils, flushing and gastrointestinal symptoms may also occur.

## PRECAUTIONS

Patients should be cautioned not to operate vehicles or hazardous machinery until their response to the drug has been determined.

## DRUG INTERACTIONS

Antidepressants, particularly of the tricyclic and monoamine oxidase inhibitor types may interact with diphenhydramine. MAO inhibitors prolong and intensify the anticholinergic effects of antihistamines. The CNS effect is increased by alcohol and other CNS depressant drugs.

## PHARMACEUTICAL PRECAUTION

Do not store above 30 °C temperature. Keep away from light and wet place. Keep out of reach of children.

## PACKAGING

### **Dorenta<sup>®</sup> 50 Tablet:**

Box containing 5 strips of 10 tablets each. Each film coated tablet contains Diphenhydramine Hydrochloride USP 50 mg.

### **Dorenta<sup>®</sup> Syrup:**

Bottle containing 100 mL syrup. Each 5 mL syrup contains Diphenhydramine Hydrochloride USP 10 mg.

# SK+F

Manufactured by

**ESKAYEF PHARMACEUTICALS LTD.**

TONGI, GAZIPUR, BANGLADESH

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