As therapy for anaphylactic reactions

Dermatographism

Cold urticaria

Mild, uncomplicated allergic skin manifestations of urticaria and angioedema.

Allergic conjunctivitis due to inhalant allergens and foods

Vasomotor rhinitis

Perennial and seasonal allergic rhinitis

This drug should not be used in newborn or premature infants.

CONTRAINDICATIONS

Newborn or Premature Infants

INDICATIONS AND USAGE

This drug should be used with caution in patients with:

- History of allergic rhinitis
- Increased intracranial pressure
- Hyperthyroidism
- Cardiovascular disease
- Hyper tension

Information for Patients

Antihistamines may diminish mental alertness; conversely, particularly in the young child, they may occasionally produce excitation. Patients should be warned about engaging in activities requiring mental alertness and motor coordination, such as driving a car or operating machinery.

Drug Interactions

Antihistamines may have additive effects with alcohol and other CNS depressants, e.g., hypnotics, sedatives, tranquillizers, antidepressants. Use with caution in patients with:

- History of allergic rhinitis
- Increased intracranial pressure
- Hyperthyroidism
- Cardiovascular disease
- Hyper tension

Information for Patients

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OVERDOSAGE

Elderly, debilitated patients

Stomach contents should be removed by gastric lavage. Because of the higher risk of antihistamines for infants generally and for newborns and premature in particular, antihistamine therapy is contraindicated in nursing mothers.

Pediatric Patients

Dysphagia, pyloric or duodenal stenosis, pyloroduodenal obstruction

Nursing Mothers

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Adverse reactions which have been reported with the use of antihistamines are as follows:

Central Nervous System
Sedation and sleepiness (often transient), dizziness, disturbed concentration, confusion, disorientation, mental depression to stimulation especially in pediatric patients. Also, atropine-like effects may occur; e.g., dry mouth; fixed, dilated pupils; flushing; increased or decreased perspiration; urinary frequency, difficult urination, urinary retention, early menses.

Respiratory
Dryness of nose and throat, thickening of bronchial secretions, tightness of chest and wheezing, nasal stuffiness.

Gastrointestinal
Dryness of mouth, nausea, vomiting, diarrhea, constipation, jaundice.

Special Senses
Photosensitivity.

Allergic manifestation of rash and edema, excessive perspiration, urticaria, pruritus.

Reproductive System
Hemolytic anemia, leukopenia, agranulocytosis, thrombocytopenia.

Other
Hypotension, palpitation, tachycardia, extrasystoles, anaphylactic shock.

Overdosage
Antihistamine overdosage reactions may vary from central nervous system depression to stimulation especially in pediatric patients. Also, atropine-like effects may occur; e.g., dry mouth; fixed, dilated pupils; flushing; increased or decreased perspiration; urinary frequency, difficult urination, urinary retention, early menses.

If vomiting has not occurred spontaneously, the patient should be induced to vomit with syrup of ipecac. If vomiting has not occurred spontaneously overdosage reaction may vary from central nervous system depression to stimulation especially in pediatric patients. Also, atropine-like effects may occur; e.g., dry mouth; fixed, dilated pupils; flushing; increased or decreased perspiration; urinary frequency, difficult urination, urinary retention, early menses.

The usual dose is 2 mg (1/2 tablet) two or three times a day, adjusted as necessary to the size and response of the patient. The dose is not to exceed to 12 mg daily.

The total daily dosage for pediatric patients may be calculated on the basis of body weight or body area using approximately 0.25 mg/kg/day or 8 mg per square meter of body surface (8 mg/m²).

Each tablet contains 4 mg of cyproheptadine hydrochloride.

Cyproheptadine Hydrochloride Tablets USP are available as white, round, flat-backed tablets, bisected and debossed "2929" below the bisect, plain on the other side, containing 4 mg of cyproheptadine hydrochloride.

HOW SUPPLIED
Cyproheptadine Hydrochloride Tablets USP are available as white, round, flat-backed, bevelled-edge tablets, packaged in bottles of 100 and 1000 tablets.

MANUFACTURED IN INDIA BY:
EMDURE PHARMACEUTICALS LTD.
Hingana, Pune, India
MADE IN INDIA
BY TELA PHARMACEUTICALS USA
Saban, PA, 19088
**TEVA PHARMACEUTICAL**

Cyproheptadine 4 mg x 100 tablets

Customer: _____________________________

P.O. No.: _____________________________

Job number: **TEV218**

Size: **A 1.575" x 4.88" (40mm x 124mm)**

Comments: _____________________________

**NOTE:** Proof colors do not represent exact PMS colors. Please check current PMS guide.

- Black
- PMS 285 Blue
- PMS 285 Blue 50%

Wind direction #3
TEVA PHARMACEUTICAL
Cyproheptadine 4 mg x 1000 tablets

Customer: __________________________
P.O. No #: __________________________
Job number: __________________________
Size: A 1.77" x 5.3149" (45mm x 135mm)
Comments: __________________________

Reviewed by: ________________________ Date: ____________
Submit Revised Proof: __________________ Date: ____________

Proof Approved By: __________________ Date: ____________