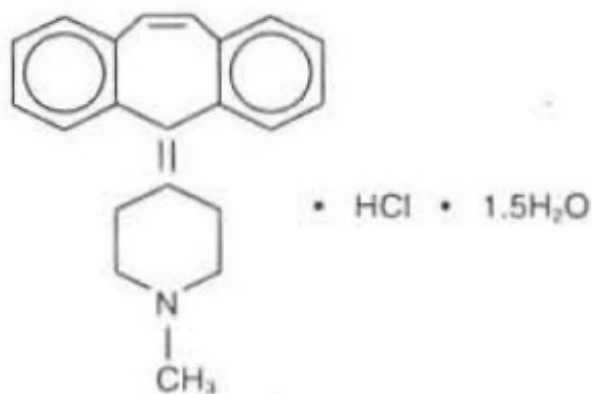


**CYPROHEPTADINE HYDROCHLORIDE- cyproheptadine hydrochloride tablet**  
**Chartwell RX, LLC**

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**CYPROHEPTADINE HCL TABLETS USP**

**DESCRIPTION:** Cyproheptadine HCl, is an antihistaminic and antiserotonergic agent.

Cyproheptadine hydrochloride is a white to slightly yellowish, crystalline, solid. with a molecular weight of 350.89, which is slightly soluble in water, freely soluble in methanol, sparingly soluble in ethanol, soluble in chloroform, and practically insoluble in ether. It is the sesquihydrate of 4-(5H-dibenzo (a, d) cyclohepten-5-ylidene)-1-methylpiperidine hydrochloride. The molecular formula of the anhydrous salt is C<sub>21</sub>H<sub>21</sub>NHCl. and the structural formula of the anhydrous salt is:



Cyproheptadine hydrochloride is available in 4 mg tablets.

**Each tablet contains:**

**Active Ingredient:**

Cyproheptadine Hydrochloride ..... 4 mg

**Each tablet contains:**

**Inactive Ingredients:**

Colloidal silicon dioxide, lactose monohydrate, magnesium stearate, microcrystalline cellulose, pregelatinized starch (corn), stearic acid.

**CLINICAL PHARMACOLOGY:**

Cyproheptadine HCl is a serotonin and histamine antagonist with anticholinergic and sedative effects. Antiserotonin and antihistamine drugs appears to compete with serotonin and histamine, respectively, for receptor sites.

**Pharmacokinetics and Metabolism:** After a single 4 mg oral dose of <sup>14</sup>C-labeled cyproheptadine HCl normal subjects given as tablets or syrup, 2-20% of the radioactivity was excreted in the stools. Only about 34% of the stool radioactivity was unchanged drug, corresponding to less than 5.7% of the dose. At least 40% of the administered radioactivity was excreted in the urine. No significant difference in the mean urinary excretion exists between the tablet and syrup formulations. No detectable amounts of unchanged drug were present in the urine of patients of chronic 12-20 mg daily doses of cyproheptadine syrup. The principal metabolite found in human urine has been identified as a quaternary ammonium glucuronide conjugate of cyproheptadine. Elimination is diminished in renal insufficiency.

**INDICATIONS AND USAGE:** Perennial and seasonal allergic rhinitis, Vasomotor rhinitis, Allergic conjunctivitis due to inhalant allergens and foods. Mild, uncomplicated allergic skin manifestations of urticaria and angioedema. Amelioration of allergic reactions to blood or plasma. Cold urticaria. Dermatographism. As therapy for anaphylactic reactions adjunctive to epinephrine and other standard measures after the acute manifestations have been controlled.

## CONTRAINDICATIONS

**Newborn or Premature Infants:** This drug should not be used in newborn or premature infants.

**Nursing Mothers:** Because of the higher risk of antihistamines for infants generally, and for newborns and prematures in particular, antihistamine therapy is contraindicated in nursing mothers.

**Other Conditions:** Hypersensitivity to cyproheptadine and other drugs of similar chemical structure. Monoamine oxidase inhibitor therapy (see DRUG INTERACTIONS). Angle-closure glaucoma. Stenosing peptic ulcer. Symptomatic prostatic hypertrophy. Bladder neck obstruction. Pyloroduodenal obstruction, elderly, debilitated patients.

## WARNINGS

**Children -** Overdosage of antihistamines, particularly in infants and children, may produce hallucinations, central nervous system depression, convulsions, and death.

Antihistamines may diminish mental alertness conversely particularly in the young child they may occasionally produce excitation.

**CNS Depressants -** Antihistamines may have additive effects with alcohol and other CNS depressants, e.g., hypnotics, sedatives, tranquilizers, antianxiety agents.

**Activities Requiring Mental Alertness -** Patients should be warned about engaging in activities requiring mental alertness and motor coordination, such as driving a car or operating machinery. Antihistamines are more likely to cause dizziness, sedation and

hypotension in elderly patients.

## **PRECAUTIONS**

**General:** Cyproheptadine has an atropine-like action and, therefore, should be used with caution in patients with History of bronchial asthma. Increased intraocular pressure, Hyperthyroidism, Cardiovascular disease, Hypertension.

**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:** MAO inhibitors prolong and intensify the anticholinergic effects of antihistamines. Antihistamines may have additive effects with alcohol and other CNS depressants, e.g., hypnotics, sedatives, tranquilizers, antianxiety agents.

**Carcinogenesis, Mutagenesis, Impairment of Fertility:** Long-term carcinogenic studies have not been done with cyproheptadine.

Cyproheptadine had no effect on fertility in a two-litter study in rats or a two generation study in mice at about 10 times the human dose. Cyproheptadine did not produce chromosome damage in human lymphocytes or fibroblasts **in vitro**; high doses ( $10^{-4}$ M) were cytotoxic. Cyproheptadine did not have any mutagenic effect in the Ames microbial mutagen test; concentrations of above 500 mcg/plate inhibited bacterial growth.

## **PREGNANCY**

**Pregnancy Category B:** Reproduction studies have been performed in rabbits, mice, and rats at oral or subcutaneous doses up to 32 times the maximum recommended human oral dose and have revealed no evidence of impaired fertility or harm to the fetus due to cyproheptadine. Cyproheptadine has been shown to be fetotoxic in rats when given by intraperitoneal injection in doses four times the maximum recommended human oral dose. Two studies in pregnant women, however, have not shown that cyproheptadine increases the risk of abnormalities when administered during the first, second and third trimesters of pregnancy. No teratogenic effects were observed in any of the newborns. Nevertheless, because the studies in humans cannot rule out the possibility of harm, cyproheptadine should be used during pregnancy only if clearly needed.

**Nursing Mothers:** It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants from cyproheptadine, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the

importance of the drug to the mother (see CONTRAINDICATIONS).

**Pediatric Use:** Safety and effectiveness in children below the age of two years have not been established. (See CONTRAINDICATIONS, Newborn or Premature infants, and WARNINGS, Children.)

## **ADVERSE REACTIONS**

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

**Central Nervous System:** Sedation and sleepiness (often transient), dizziness, disturbed coordination, confusion, restlessness, excitation, nervousness, tremor, irritability, insomnia, paresthesias, neuritis, convulsions, euphoria, hallucinations, hysteria, faintness.

**Integumentary:** Allergic manifestation of rash and edema, excessive perspiration, urticaria, photosensitivity.

**Special Senses:** Acute labyrinthitis, blurred vision, diplopia, vertigo, tinnitus.

**Cardiovascular:** Hypotension, palpitation, tachycardia, extrasystoles, anaphylactic shock.

**Hematologic:** Hemolytic anemia, leukopenia, agranulocytosis, thrombocytopenia.

**Digestive System:** Dryness of mouth, epigastric distress, anorexia, nausea, vomiting, diarrhea, constipation, jaundice.

**Genitourinary:** 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.

**Miscellaneous:** Fatigue, chills, headache, increased appetite/weight gain.

**OVERDOSAGE:** Antihistamine overdosage reactions may vary from central nervous system depression to stimulation, especially in children. Also, atropine-like signs and symptoms (dry mouth; fixed, dilated pupils; flushing, etc.) as well as gastrointestinal symptoms may occur.

If vomiting has not occurred spontaneously, the patient should be induced to vomit with syrup of ipecac. If patient is unable to vomit, perform gastric lavage followed by activated charcoal. Isotonic or 1/2 isotonic saline is the lavage of choice. Precautions against aspiration must be taken, especially in infants and children.

When life threatening CNS signs and symptoms are present, intravenous physostigmine salicylate may be considered. Dosage and frequency of administration are dependent on age, clinical response, and recurrence after response. (See package circulars for physostigmine products).

Saline cathartics, as milk of magnesia, by osmosis draw water into the bowel and therefore are valuable for their action in rapid dilution of bowel content.

Stimulants should not be used.

Vasopressors may be used to treat hypotension.

The oral LD<sub>50</sub> of cyproheptadine is 123 mg/kg, and 295 mg/kg in the mouse and rat, respectively.

**DOSAGE AND ADMINISTRATION:** DOSAGE SHOULD BE INDIVIDUALIZED ACCORDING TO THE NEEDS AND THE RESPONSE OF THE PATIENT.

**Children:** The total daily dosage for children may be calculated on the basis of body weight or body area using approximately 0.25 mg/kg/day (0.11 mg/lb/day) or 8 mg per square meter of body surface (8 mg/m<sup>2</sup>). In small children for whom the calculation of the dosage based upon body size is important, it may be necessary to use cyproheptadine syrup to permit accurate dosage.

**Age 2 to 6 years:** 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 12 mg a day.

**Age 7 to 14 years:** The usual dose is 4 mg (1 tablet) two or three times a day, adjusted as necessary to the size and response of the patient. The dose is not to exceed 16 mg a day.

**Adults:** The total daily dose for adults should not exceed 0.5 mg/kg/day (0.23 mg/lb/day).

The therapeutic range is 4 to 20 mg a day, with the majority of patients requiring 12 to 16 mg, a day. An occasional patient may require as much as 32 mg a day for adequate relief. It is suggested that dosage be initiated with 4 mg (1 tablet) three times a day and adjusted according to the size and response of the patient.

**HOW SUPPLIED:** Each tablet contains 4 mg of cyproheptadine hydrochloride, are white to off-white, round, flat faced, beveled edge tablets debossed with "CE 73" on one side and a score on other side. They are supplied as follows: bottles of 90 count, NDC 62135-236-90.

**Dispensing Information:** Dispense in tight containers as defined by the USP/NF.

**Caution:** Federal law prohibits dispensing without prescription. KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Manufactured for:

Chartwell RX, LLC

Congers, NY 10920

Telephone Number-1-845-232-1683

L70791

Rev. 01/2023

# PACKAGE LABEL-PRINCIPAL DISPLAY PANEL

## Cyproheptadine Hydrochloride Tablets, USP 4 mg NDC 62135-236-90 - 90s Bottle Label

NDC 62135-236-90

# Cyproheptadine Hydrochloride Tablets, USP

**4 mg**

**Rx Only**  
**90 Tablets**

**Chartwell Rx**

Each tablet contains 4 mg Cyproheptadine Hydrochloride, USP.  
**Usual Dosage:** See package insert for full prescribing information.  
**Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].**  
Dispense in a well-closed, light-resistant container as defined in the USP, with a child-resistant closure (as required).  
Protect from moisture.  
**KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.**

Manufactured For: Chartwell RX, LLC.  
Congers, NY 10920

GTIN 00362135236908 L70793 REV. 01 01/23



**No Varnish**

## CYPROHEPTADINE HYDROCHLORIDE

cyproheptadine hydrochloride tablet

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:62135-236
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>CYPROHEPTADINE HYDROCHLORIDE</b> (UNII: NJ82J0F8QC) (CYPROHEPTADINE - UNII:2YHB6175DO)	CYPROHEPTADINE HYDROCHLORIDE	4 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	

### Product Characteristics

<b>Color</b>	white (Off White)	<b>Score</b>	2 pieces
<b>Shape</b>	ROUND	<b>Size</b>	7mm

<b>Flavor</b>		<b>Imprint Code</b>	CE73	
<b>Contains</b>				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62135-236-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/05/2023	
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA088212	05/26/1983		

**Labeler** - Chartwell RX, LLC (079394054)

### Establishment

Name	Address	ID/FEI	Business Operations
Chartwell Pharmaceuticals Congers, LLC		118673447	analysis(62135-236) , label(62135-236) , manufacture(62135-236) , pack(62135-236)

Revised: 1/2023

Chartwell RX, LLC