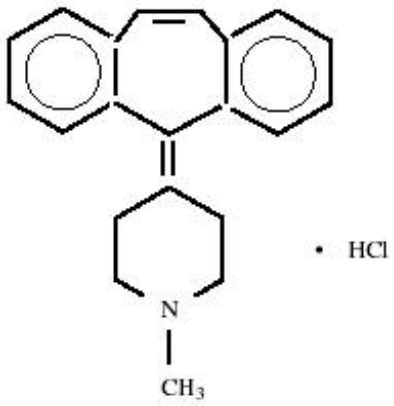
CYPROHEPTADINE HYDROCHLORIDE- cyproheptadine hydrochloride tablet
REMEDYREPACK INC.

Cyproheptadine Hydrochloride Tablets, USP
(4 mg)
Rx only

DESCRIPTION

Cyproheptadine hydrochloride is an antihistaminic and antiserotonergic agent.

Cyproheptadine hydrochloride, USP is a white to slightly yellowish crystalline solid, with a molecular weight of 350.89, which is 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-(5 *H*-dibenzo *[a,d]*cyclohepten-5-ylidene)-1-methylpiperidine hydrochloride. The molecular formula of the anhydrous salt is $C_{21}H_{21}N$•HCl and the structural formula of the anhydrous salt is:



$C_{21}H_{21}N$•HCl
M.W. 350.89

Cyproheptadine hydrochloride, USP is available for oral administration in 4 mg tablets. Inactive ingredients include: lactose monohydrate, magnesium stearate, microcrystalline cellulose, and pregelatinized starch.

CLINICAL PHARMACOLOGY

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

Pharmacokinetics and Metabolism

After a single 4 mg oral dose of ^{14}C-labelled cyproheptadine hydrochloride in normal subjects, given as tablets, 2% to 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 detectable amounts of unchanged drug were present in the urine of patients on chronic 12 mg to 20 mg daily doses. The principle 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

Pediatric Patients

*Overdosage*of antihistamines, particularly in infants and young children, may produce hallucinations, central nervous system depression, convulsions, respiratory and cardiac arrest, 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 (see **PRECAUTIONS**,**Geriatric Use**).

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.

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625 Kolter Drive, Indiana, PA 15701

(724) 465-8762

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 pediatric patients below the age of two have not been established (see **CONTRAINDICATIONS**,**Newborn or Premature Infants**, and **WARNINGS**,**Pediatric Patients**).

Geriatric Use

Clinical studies of cyproheptadine hydrochloride tablets did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy (see **WARNINGS**,**Activities Requiring Mental Alertness**).

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

Cholestasis, hepatic failure, hepatitis, hepatic function abnormality, 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.

To report SUSPECTED ADVERSE REACTIONS, contact Amneal Pharmaceuticals at 1-877-835-5472 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

OVERDOSAGE

Antihistamine overdosage reactions may vary from central nervous system depression

to stimulation especially in pediatric patients. 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 ½ 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_{50} 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.

Each tablet contains 4 mg of cyproheptadine hydrochloride.

Pediatric Patients

Age 2 to 6 years

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/m^2).

The usual dose is 2 mg (½ 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. The therapeutic range is 4 mg to 20 mg a day, with the majority of patients requiring 12 mg 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.

Cyproheptadine hydrochloride tablets USP, 4 mg are supplied as white, round, compressed tablets. Engraved "cor" above the bisect and "150" below the bisect on one side and plain on the other side.

They are supplied as follows:

NDC: 70518-4667-00

NDC: 70518-4667-01

PACKAGING: 50 in 1 BOX

PACKAGING: 1 in 1 POUCH

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Dispense in a well-closed container as defined in the USP. Use child-resistant closure (as required).

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Repackaged and Distributed By:

Remedy Repack, Inc.

625 Kolter Dr. Suite #4 Indiana, PA 1-724-465-8762

DRUG: Cyproheptadine Hydrochloride

GENERIC: Cyproheptadine Hydrochloride

DOSAGE: TABLET

ADMINSTRATION: ORAL

NDC: 70518-4667-0

NDC: 70518-4667-1

COLOR: white

SHAPE: ROUND

SCORE: Two even pieces

SIZE: 7 mm

IMPRINT: cor;150

PACKAGING: 1 in 1 POUCH

OUTER PACKAGING: 50 in 1 BOX

ACTIVE INGREDIENT(S):
- CYPROHEPTADINE HYDROCHLORIDE 4mg in 1

INACTIVE INGREDIENT(S):
- LACTOSE MONOHYDRATE
- MAGNESIUM STEARATE
- CELLULOSE, MICROCRYSTALLINE

- STARCH, CORN

Cyproheptadine HCl Tablet

MFG NDC: 00115-1757-01
MFG: Amneal Pharma, Glasgow, KY 42141

Usual Dosage: See Insert

Keep this and all medication out o the reach of children
Store at 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F) [See USP]

4 mg

QTY: 50 Per Box
NDC #: **70518-4667-00**
LOT #:
Expires:
Round WHITE cor;150

remedy repack

RX ONLY

Repackaged By: RemedyRepack Inc.,
Indiana, PA 15701, 724.465.8762

Cyproheptadine HCl Tablet

MFG NDC: 00115-1757-01
MFG: Amneal Pharma, Glasgow, KY 42141

Usual Dosage: See Insert

Keep this and all medication out o the reach of children
Store at 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F) [See USP]

4 mg

QTY: 1 Tablet
NDC #: **70518-4667-01**
LOT #:
Expires:
Round WHITE cor;150

remedy repack

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CYPROHEPTADINE HYDROCHLORIDE

cyproheptadine hydrochloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70518-4667(NDC:0115-1757)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CYPROHEPTADINE HYDROCHLORIDE (UNII: NJ82J0F8QC) (CYPROHEPTADINE - UNII:2YHB6175DO)	CYPROHEPTADINE HYDROCHLORIDE	4 mg

Inactive Ingredients	
Ingredient Name	**Strength**
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	white	**Score**	2 pieces
Shape	ROUND	**Size**	7mm
Flavor		**Imprint Code**	cor;150
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70518-4667-0	50 in 1 BOX	05/27/2026	
1	NDC:70518-4667-1	1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040537	05/27/2026	

Labeler - REMEDYREPACK INC. (829572556)

Revised: 6/2026 REMEDYREPACK INC.