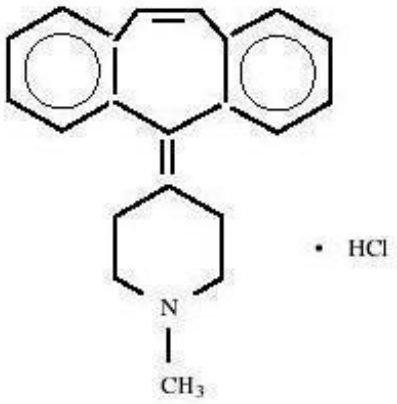
CYPROHEPTADINE HYDROCHLORIDE- cyproheptadine hydrochloride tablet
Apnar Pharma

Cyproheptadine Hydrochloride Tablets, USP

DESCRIPTION

Cyproheptadine HCl USP 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-(5H-dibenzo[a,d]cyclohepten-5-ylidene)-1-methylpiperidine hydrochloride. The molecular formula of the anhydrous salt is $C_{21}H_{21}N \cdot HCl$ and the structural formula of the anhydrous salt is:



$C_{21}H_{21}N \cdot HCl$ 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 sodium starch glycolate.

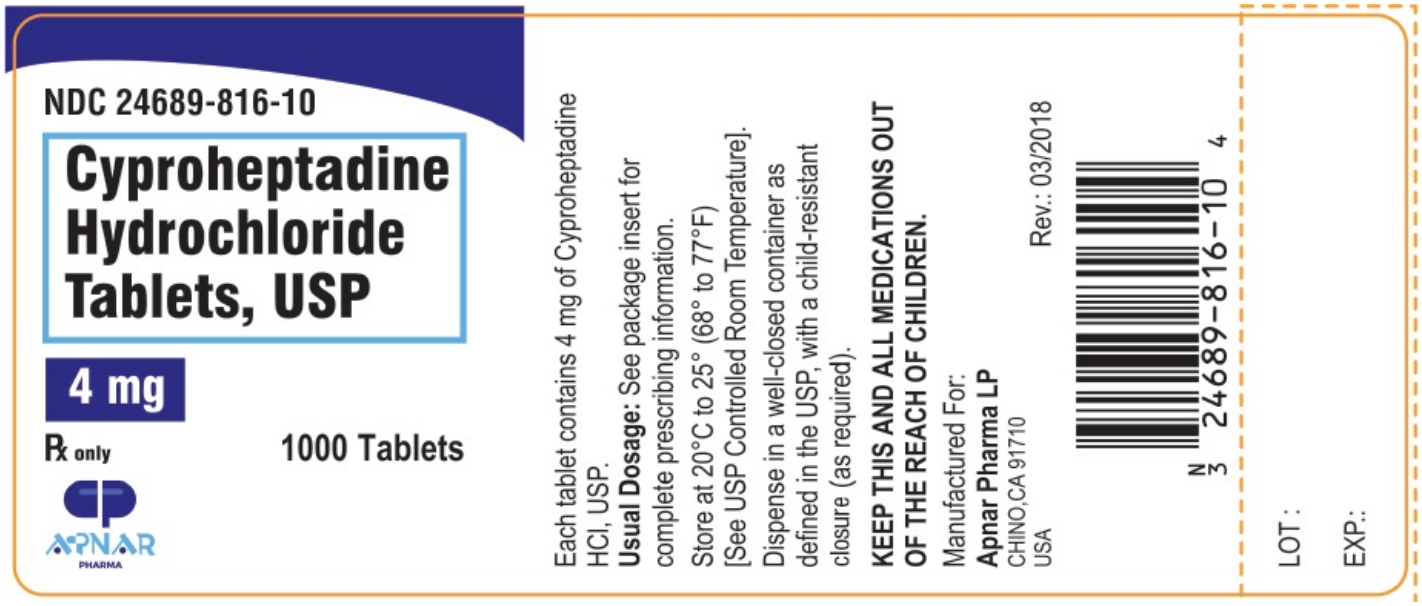
CLINICAL PHARMACOLOGY

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 14C-labelled cyproheptadine HCl 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 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.

Cyproheptadine HCl Tablets USP 4mg



CYPROHEPTADINE HYDROCHLORIDE

cyproheptadine hydrochloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:24689-816
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)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	white	**Score**	2 pieces
Shape	ROUND	**Size**	7mm
Flavor		**Imprint Code**	IT;68
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24689-816-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/21/2018	
2	NDC:24689-816-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	05/21/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207555	05/15/2018	

Labeler - Apnar Pharma (079568229)

Establishment

Name	Address	ID/FEI	Business Operations
InvaTech Pharma Solutions LLC		078602180	manufacture(24689-816) , analysis(24689-816)

Revised: 5/2021 Apnar Pharma