1. NAME OF THE MEDICINALPRODUCT

CETOPRON (Cyproheptadine Tablet BP 4 mg)

2. QUALITATIVE AND QUANTITATIVECOMPOSITION

Description: Orange-coloured elongated sugar coated having printed "CETOPRON" on one side of each Tablet.

Label Claim:

Each sugar-coated tablet contains:
Cyproheptadine HCL BP 4 mg

Pack Size: Alu-PVC blister pack of 10 tablets.

Sr. No.	Ingredients	Specification	Quantity /Tablet (mg)	% Overages	Quantity /batch (kg)	Reason for inclusion
1.	Cyproheptadine hcl BP equ.to Cyproheptadine HCL anhydrous	BP	4.585	---	404.00	Active
2.	Iso-P ropyl alcohol BP	BP		---	1.5	*Solvent*
3.	Ennar dummy granules Whiteih	BP	556.049	---	341.97	_____
4.	Talcum BP	BP	7.967	---	4.9	Glidant
5.	Mag. Stearate BP	BP	2.927	---	1.8	Lubricant
6.	Aerosil BP	BP	3.984	---	2.45	Glidant
7.	Microcrystalline cellulose Bp	BP	5.967	---	3.67	Binder/ Diluent
8.	Saline infusion sonohysterography Bp	BP	2.000	---	1.23	_____
9.	Sodium starch glycolate Bp	BP	9 .919	---	6.1	Binder
10	Sugar coating	BP		---		Diluent
11	Sub coating: 1) sugar bp	BP	72.358	---	44.5	Diluent
12	2) gelatin bp	BP	2.537	---	1.6	Active
13	3) pvp k-30 bp	BP	1.220	---	0.75	Binder
14	4) methyl paraben bp	BP	0.049	---	0.03	Preservative

15	5) propyl paraben bp	BP	0.005	---	0.003	Preservative
16	6)Calcium propionate BP	BP	0.049	---	0.3	Preservative
17	Dusting Stage: 1) Purified talc BP	BP	65.366	---	40.2	Glidant
18	2) Calcium carbonates BP	BP	65.366	---	40.2	Glidant
19	Pasting: 1) talcip	BP	16.504	---	10.15	Binder
20	2)Calcium carbonate BP	BP	16.504	---	10.15	Binder
21	3)Titanium oxide BP	BP	0.894	---	0.55	_____
22	4)sugar Bp	BP	72.358	---	44.5	Diluent
23	5)gelatin Bp	BP	1.56	---	1.56	Binder
24	6)Colour sunset yellow supraih	BP	0.195	---	0.12	Colouring agent
25	7) pvpk – 30 Bp	BP	1.220	---	0.75	Binder
26	Smoothing: 1) sugar Bp	BP	8.163	---	5.02	Flavoring
27	2) gelatin bp	BP	0.488	---	0.3	Binder
28	Colour coat: 1) sugar bp	BP	28.260	---	17.38	Colouring agent
29	2) gelatin bp	BP	1.626	---	0.6	Colouring agent
30	3) colour sunset yellow supraih	BP	0.390	---	0.24	Colouring agent
31	Polishing: 1) carnauba wax bp	BP	0.407	---	0.25	Polishing
32	2) bees wax bp	BP	0.203	**---**	0.125	Polishing
33	3) Methylene dichloride BP	BP	16 .325	**---**	10.04	Polishing

3. PHARMACEUTICAL FORM

Orange-colored elongated sugar-coated having printed "CETOPRON" on one side of each Tablet.

4.Clinical particulars

4.1 Therapeuticindications

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.

4.2 Posology and method ofadministration

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 2 square meter of body surface (8 mg/m). 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. 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.

4.3 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.

4.4 Special warnings and precautions foruse

Lactic acidosis:

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.

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.

4.5 Interaction with other medicinal products and other forms ofinteraction

Drug Interaction

MAO inhibitors prolong and intensify the anti-cholinergic effects of antihistamines. Antihistamines may have additive effects with alcohol and other CNS depressants, e.g., hypnotics, sedatives, tranquilizers, anti-anxiety 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.

4.6 Pregnancy and Lactation

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.

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.

4.7 Effects on ability to drive and usemachines
Study is not found.

4.8 Undesirableeffects

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.

4.9 Overdose
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 1/2 isotonic saline is the lavage of choice. Precautions against aspiration must be taken especially in infants and children.
Vasopressors may be used to treat hypotension. The oral LD50 of cyproheptadine is 123 mg/kg, and 295 mg/kg in the mouse and rat, respectively.

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.

5.0 PHARMACOLOGICALPROPERTIES

5.1 Pharmacodynamics properties

Pharmacotherapeutic group: Antihistaminic.
ATC code: R06AX02
Mode of action
Serotonin and histamine antagonist; competitively inhibits H1 receptor, mediating bronchial constriction, smooth-muscle contraction, edema, hypotension, CNS depression, and cardiac arrhythmias; prevents histamine release in blood vessels and is more effective in preventing histamine response than in reversing it; may be useful in patients with syndromes sustained by histamine-producing tumors.
Moderate anticholinergic activity with low sedative effect May have anti-5HT2 effects.

5.2 Pharmacokinetic properties

Absorption
Peak plasma time: 6-9 hr

Metabolism
Metabolized by glucuronidation via UGT1A
Metabolites: Quaternary ammonium glucuronide conjugate
Elimination

Excretion: Urine (40%), feces (2-20%)

5.3Preclinical safety data

Preclinical data reveals no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential and reproductive toxicity.

6.0 PHARMACEUTICALPARTICULARS

The results of the preclinical tests do not add anything of further significance to the prescriber.

6.1 List of EXCIPIENT:

SR NO:	INGRED IENTS		Reason for Inclusion
1.	Starch bp		Binder
2.	Iso-P ropyl alcohol BP		Solvent
3.	Ennar dummy granules Whiteih		_____
4.	Talcum BP		Glidant
5.	Mag. Stearate BP		Lubricant
6.	Aerosil BP		Glidant
7.	Microcrystalline cellulose Bp		Binder/ Diluent
8.	Saline infusion sonohysterography Bp		_____
9.	Sodium starch glycolate Bp		Binder
10.	Total		
11.	Sugar coating		Diluent
12.	Sub coating: 1) sugar bp		Diluent
13.	2) gelatin bp		Binder

14.	3) pvp k-30 bp		Binder
15.	4) methyl paraben bp		Preservative
16.	5) propyl paraben bp		Preservative
17.	6)Calcium propionate BP		Preservative
18.	Dusting Stage: 1) Purified talc BP		Glidant
19.	2) Calcium carbonates BP		Glidant
20.	Pasting: 1) talcip		Binder
21.	2)Calcium carbonate BP		Binder
22.	3)Titanium oxide BP		_____
23.	4)sugar Bp		Diluent
24.	5)gelatin Bp		Binder
25.	6)Colour sunset yellow supraih		Colouring agent
26.	7) pvpk – 30 Bp		Binder
27.	Smoothing: 1) sugar Bp		Flavoring
28.	2) gelatin bp		Binder
29.	Colour coat: 1) sugar bp		Colouring agent
30.	2) gelatin bp		Colouring agent
31.	3) colour sunset yellow supraih		Colouring agent
32.	Polishing: 1) carnauba wax bp		Polishing
33.	2) bees wax bp		Polishing
34.	3) Methylene dichloride BP		Polishing

6.2 Shelflife :36 months

6.3 Special precautions forstorage

Store below 30ºC. Protect from light. Keep all medicines away from reach of children.

6.4 Nature and contents of container

Alu- PVC blister of 10 tablets each, such 10 blisters are packed in a primary carton along with pack insert.

6.5 Special precautions for disposal and otherhandling

Not applicable

7 . APPLICANT/MANUFACTURER

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