

1.6 Product Information

1.6.1 PRESCRIBING INFORMATION (SUMMARY OF PRODUCTS CHARACTERISTICS)

(SPC, CONTAINER LABELING & PATIENT INFORMATION LEAFLET, MOCK-UPS AND SPECIMENS)

SPC – Summary of the Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

CYPROL Syrup (Cyproheptadine Hydrochloride & Lysine Hydrochloride syrup)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:

Cyproheptadine Hydrochloride BP	2 mg
Lysine Hydrochloride BP	150 mg
Colour: Riboflavin	
Flavoured Syrupy base	q.s

3. PHARMACEUTICAL FORM

Oral Syrup

CYPROL Syrup (Cyproheptadine Hydrochloride & Lysine Hydrochloride syrup) is a yellow coloured flavoured syrup

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

CYPROL Syrup is a medicine that is used for the treatment of Allergies, Sneezing, Watery eyes, Itching and runny nose, Loss of appetite, Migraine and vascular headache and other conditions.

4.2 Posology and method of administration

5 ml (1 Teaspoon full) two to three times a day.

4.3 Contraindications

Hypersensitivity to CYPROL Syrup is a contraindication. In addition, CYPROL Syrup should not be taken if you have the following conditions:

- Angle-closure glaucoma
- Bladder neck obstruction
- Breastfeeding
- Cyproheptadine and other drugs of similar chemical structure
- Elderly or debilitated patients

- Monoamine oxidase inhibitor therapy

4.4 Special warnings and precautions for use.

Before using this drug, inform your doctor about your current list of medications, over the counter products (e.g. vitamins, herbal supplements, etc.), allergies, pre-existing diseases, and current health conditions (e.g. pregnancy, upcoming surgery, etc.). Some health conditions may make you more susceptible to the side effects of the drug. Take as directed by your doctor or follow the direction printed on the product insert. Dosage is based on your condition. Tell your doctor if your condition persists or worsens. Important counseling points are listed below.

- Avoid drinking alcohol as it can increase certain side effects
- Consult your doctor before taking this medicine if you are pregnant
- Do not start or continue the drug without consulting
- Do not take this medicine while you are breastfeeding
- If you are allergic to it or any of the other ingredients
- If you are taking other medicines such as antihistamines or monoamine-oxidase inhibitors

4.5 Interaction with other medicinal products and other forms of interaction

If you take other drugs or over the counter products at the same time, the effects of CYPROL Syrup may change. This may increase your risk for side effects or cause your drug not to work properly. Tell your doctor about all the drugs, vitamins, and herbal supplements you are using, so that you doctor can help you prevent or manage drug interactions. CYPROL Syrup may interact with the following drugs and products:

- Alcohol
- Aminoglycosides
- Antibiotics
- Arginine
- Atropine
- Barbiturates

4.6 Pregnancy and lactation

Please consult with your doctor for case-specific recommendations.

4.7 Effects on ability to drive and use machines

If you experience drowsiness, dizziness, hypotension or a headache as side-effects when eating CYPROL Syrup medicine then it may not be safe to drive a vehicle or operate heavy machinery. One should not drive a vehicle if eating the medicine makes you drowsy, dizzy or lowers your blood-pressure extensively. Pharmacists also advise patients not to drink alcohol with medicines as alcohol intensifies drowsiness side-effects. Please check for these effects on your body when using CYPROL Syrup. Always consult with your doctor for recommendations specific to your body and health conditions.

CYPROL Syrup
(Cyproheptadine Hydrochloride & Lysine Hydrochloride syrup)
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4.8 Overdose

Do not take more than prescribed dose. Taking more medication will not improve your symptoms; rather they may cause poisoning or serious side effects. If you suspect that you or anyone else who may have overdosed of CYPROL Syrup, please go to the emergency department of the closest hospital or nursing home. Bring a medicine box, container, or label with you to help doctors with necessary information.

Do not give your medicines to other people even if you know that they have the same condition or it seems that they may have similar conditions. This may lead to overdosage.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Cyproheptadine Hydrochloride

ATC Code: R06AX02

Cyproheptadine is a piperidine antihistamine. Unlike other antihistamines, this drug also antagonizes serotonin receptors. This action makes Cyproheptadine useful in conditions such as vascular headache and anorexia. Cyproheptadine does not prevent the release of histamine but rather competes with free histamine for binding at HA-receptor sites. Cyproheptadine competitively antagonizes the effects of histamine on HA-receptors in the GI tract, uterus, large blood vessels, and bronchial smooth muscle. Most antihistamines possess significant anticholinergic properties, but Cyproheptadine exerts only weak anticholinergic actions. Blockade of central muscarinic receptors appears to account for Cyproheptadine's antiemetic effects, although the exact mechanism is unknown. Cyproheptadine also competes with serotonin at receptor sites in smooth muscle in the intestines and other locations. Antagonism of serotonin on the appetite center of the hypothalamus may account for Cyproheptadine's ability to stimulate appetite. Cyproheptadine also has been used to counter vascular headaches, which many believe are caused by changes in serotonin activity; however it is unclear how Cyproheptadine exerts a beneficial effect on this condition.

Mechanism of action

Cyproheptadine competes with free histamine for binding at HA-receptor sites. This antagonizes the effects of histamine on HA-receptors, leading to a reduction of the negative symptoms brought on by histamine HA-receptor binding. Cyproheptadine also competes with serotonin at receptor sites in smooth muscle in the intestines and other locations. Antagonism of serotonin on the appetite center of the hypothalamus may account for Cyproheptadine ability to stimulate appetite.

Lysine

ATC Code: B05XB03

Insures the adequate absorption of calcium; helps form collagen (which makes up bone cartilage & connective tissues); aids in the production of antibodies, hormones & enzymes. Recent studies have shown that Lysine may be effective against herpes by improving the balance of nutrients that reduce viral growth. A deficiency may result in tiredness, inability to concentrate, irritability, bloodshot eyes, retarded growth, hair loss, anemia & reproductive problems.

Mechanism of action

Proteins of the herpes simplex virus are rich in L-arginine, and tissue culture studies indicate an enhancing effect on viral replication when the amino acid ratio of L-arginine to L-lysine is high in the tissue culture media. When the ratio of L-lysine to L-arginine is high, viral replication and the cytopathogenicity of herpes simplex virus have been found to be inhibited. L-lysine may facilitate the absorption of calcium from the small intestine.

5.2 Pharmacokinetic properties

Cyproheptadine Hydrochloride

Absorption: well absorbed after oral administration.

Protein binding: 96 to 99%\

Metabolism: Hepatic (cytochrome P-450 system) and some renal.

Route of elimination : 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. At least 40% of the administered radioactivity was excreted in the urine.

Lysine

Absorbed from the lumen of the small intestine into the enterocytes by an active transport process.

5.3 Preclinical safety data

Not available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Sr. No.	Ingredients	Specification
1.	Sucrose	BP
2.	Propylene Glycol	BP
3.	Methyl Hydroxybenzoate	BP
4.	Propyl Hydroxybenzoate	BP
5.	Saccharin	BP
6.	Sodium Benzoate	BP
7.	Essence Mixed Fruit Flavour	IHS
8.	Disodium Edetate	BP
9.	Riboflavin Sodium Phosphate	BP
10.	Purified Water	BP

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store below 30°C in dark place. Do not freeze.

6.5 Nature and contents of container

100 ml Amber Colour PET Bottle

6.6 Special precautions for disposal

No special requirements

7. MARKETING AUTHORISATION HOLDER

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(Cyproheptadine Hydrochloride & Lysine Hydrochloride syrup)
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8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT