

Oraxin[®]

Composition:

Each 5ml of Oraxin syrup contains

Cyproheptadine 2mg

Tricholine citrate 275mg

Each ml of Oraxin drops contains

Cyproheptadine 1.5mg

Tricholine citrate 55mg

Pharmacokinetic properties:

After absorption from the gastrointestinal tract, cyproheptadine hydrochloride undergoes almost complete metabolism. Metabolites are excreted principally in the urine as conjugates, and also in the faeces.

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's ability to stimulate appetite.

Tricholine citrate contains three molecules of choline. Clinical interest in choline centers on its lipotropic action & its utility in the treatment of fatty infiltration and cirrhosis of liver. Choline converts fat into phospholipids like, lecithin, which is essential to bio membrane structure and its function. Lecithin is also a major component of high density lipoprotein (HDL), and is used to mobilize cholesterol from cell membrane. In patients with fatty liver, increased rate of phospholipid turnover has been observed following administration of choline.

Other pharmacodynamic properties:

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



We Impart Health to Life

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.

Indication:

- ORAXIN is indicated for loss of appetite, weight loss, anorexia nervosa, and as an adjunct to anti-tubercular and antiretroviral regimens for weight gain.
- In children, ORAXIN is indicated in underweight children who have inadequate dietary intake or loss of appetite and children suffering from anemia, liver or digestive disorder.

Contraindication:

Use of ORAXIN is contraindicated in newborn or premature infants. Other contraindications to ORAXIN include hypersensitivity to any ingredient of formulation, angle-closure glaucoma, stenosing peptic ulcer, symptomatic prostatic hypertrophy, bladder neck obstruction and pyloroduodenal obstruction.

Drug Interaction:

- MAO inhibitors prolong and intensify the anticholinergic effects of antihistamines.
- ORAXIN may have additive effects with alcohol and other CNS depressants like, hypnotics, sedatives, tranquilizers and antianxiety agents.

Adverse effects:

Adverse reactions associated with ORAXIN can be attributed to cyproheptadine. These may include sedation (often transient), dizziness, disturbed coordination, confusion, restlessness; rash, urticaria; blurred vision, diplopia, vertigo, tinnitus; hypotension, palpitation, tachycardia; dryness of mouth, anorexia, diarrhea, constipation, urinary retention; dryness of nose and throat and thickening of bronchial secretions.

Warnings and Precautions:

- Cyproheptadine has an atropine-like action therefore, should be used with caution in patients with history of bronchial asthma, increased intraocular pressure, hyperthyroidism, cardiovascular disease and hypertension.
- 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.



We Impart Health to Life

- Overdose of antihistamines, particularly in infants and children, may produce hallucinations, central nervous system depression, convulsions and death.
- Antihistamines are more likely to cause dizziness, sedation and hypotension in elderly.

Use in special population:

- 1. Pediatric:** Safe in children of age above 1 year.
- 2. Geriatric:** Avoid use in elderly because of high incidence of anticholinergic effects; may exacerbate existing lower urinary conditions or benign prostatic hyperplasia; if used, administer at low end of dosage range
- 3. Liver impairment:** Use with caution.
- 4. Renal failure:** Use with caution.
- 5. Pregnancy and lactation:** Cyproheptadine falls under the FDA's Pregnancy Category B, which means that harm to a developing fetus is unlikely. It's not recommended that breastfeeding mothers take cyproheptadine. Consultation with doctor is recommended in breastfeeding.

Dosage:

The recommended doses for cyproheptadine are 0.25 mg/kg/dose that have to be taken twice or thrice a day. It has been proved to be safe even for children less than 2 years of age. The recommended dose of Oraxin drops should be:

Age	Concentration of drops (mg)	Volume of drops(ml)
Upto 6 months	0.75 mg	0.5 ml
6 – 12 months	1.5 mg	1 ml
1- 2 years	1.5 – 3 mg	1 -2 ml

Presentation:

Oraxin Syrup in presented in 100 ml / 200 ml bottle

Oraxin Drops in presented in 15 ml bottle with calibrated dropper

Storage and handling:

Store in cool and dry place.



We Impart Health to Life