

Cypro-Vita®

Film-coated tablets

(Cyproheptadine Hydrochloride with multivitamins)

INDICATIONS

Cypro-Vita® is indicated in symptomatic relief of hypersensitivity reactions including urticaria, angioedema, rhinitis and conjunctivitis, and in pruritic skin disorders. It has antimuscarinic and central sedative activity.

It is used in the prophylaxis and treatment of vascular and migraine headaches.

It is indicated for the control of diarrhea associated with the carcinoid syndrome.

The adjuvant of the vitamins to Cyproheptadine HCl prevents development of vitamin deficiencies.

DOSAGE AND ADMINISTRATION

Cypro-Vita® is available as film-coated, orange, round tablets, plain on one side, engraved "ALG CVIT" on the other.

Each tablet contains:

Cyproheptadine HCl	4.00 mg
Vit. A	1670.00 IU
Vit. D ₃	167.00 IU
Thiamine mononitrate (Vit. B ₁)	0.60 mg
Riboflavin (Vit. B ₂)	0.75 mg
Pyridoxine HCl (Vit. B ₆)	0.60 mg
Cyanocobalamin (Vit. B ₁₂)	2.50 mg
Niacinamide	5.00 mg
Ascorbic acid (Vit. C)	20.00 mg

Excipients: lactose, cellulose microcrystalline, colloidal silicon dioxide, magnesium stearate, ethanol, hydroxypropyl methylcellulose, methylene chloride, Polyethylene glycol 400, titanium dioxide, FD&C yellow # 6.

Hypersensitivity Reactions and Pruritis:

Adults: 1 tablet three times a day by mouth ;

Maximum dosage of 8 tablets per day may be used occasionally.

Children 7 to 14 years: 1 tablet two or three times a day ; Maximum of 4 tablets per day.

Children 2 to 6 years: Half a tablet two or three times a day ; Maximum of 3 tablets per day.

Vascular and Migraine Headaches:

A dose of 1 tablet is used for vascular and migraine headaches and may be repeated after 30 minutes; a maintenance dose of 1 tablet may be given every 4 to 6 hours.

Carcinoid Syndrome:

As serotonin antagonist it helps relieving the diarrhea associated with carcinoid syndrome in doses of one to two tablets every 6 hours.

Prevention of Hypovitaminosis:

Each tablet provides quantities of the vitamins required for the prevention of hypovitaminosis.

USES

Cypro-Vita® is a histamine H₁-receptor antagonist and serotonergic antagonist. As such it is used for the symptomatic relief of hypersensitivity reactions as well as in pruritic skin disorders. Other uses are relief of migraine.

Vit. C is essential for the synthesis of collagen and intercellular material.

Vit. A is essential for the growth, development and maintenance of epithelial tissue and for vision.

Vit. D₃ is essential for proper regulation of calcium and phosphate homeostasis and bone mineralisation.

Vit. B₁ (Thiamine) is an essential coenzyme for carbohydrate metabolism.

Vit. B₂ (Riboflavin) is essential for utilization of energy from food.

Vit. B₁₂ is important for the proper functioning of the nervous system.

Vit. B₆ is involved mainly in amino acid metabolism. It is also involved in carbohydrate and fat metabolism. It is required for the formation of haemoglobin.

Niacinamide in the form of NAD and NADP Coenzymes is involved in electron transfer reactions in the respiratory chain.

ADVERSE EFFECTS - SIDE EFFECTS OF ANTIHISTAMINES

Sedation effect:

The most common side-effect of antihistamines is sedation, varying from drowsiness to deep sleep. These may diminish after a few days of treatment. Paradoxical CNS stimulation may occur especially in children with irritability, insomnia, tremors.

Antimuscarinic effect:

Histamine H₁-Receptor antagonists possess antimuscarinic properties: dry mouth, thickened respiratory-tract secretions and tightness of the chest, blurred vision, urinary difficulty, reduction in tone and motility of gastro-intestinal tract resulting in constipation and increased gastric reflux; in high doses transient bradycardia followed by tachycardia with palpitations and arrhythmias.

Blood disorders :

Rare blood disorders have been reported. These include agranulocytosis, leucopenia, haemolytic anemia.

Foetal abnormalities:

Various antihistamines have been associated with foetal abnormalities when taken during pregnancy.

Overdose:

Overdose may be fatal specially in infants and children. CNS stimulation predominates over CNS depression causing ataxia, tremors, excitement, psychoses, hallucinations and convulsions. In adults CNS depression is more common with drowsiness, coma and convulsions progressing to respiratory failure or possibly cardio-vascular collapse.

TREATMENT OF ADVERSE EFFECT OF H₁ - RECEPTOR ANTAGONISTS (Antihistamines)

- 1- The stomach should immediately be emptied.
- 2- Emetics may be administered if patient is conscious.
- 3- Activated charcoal has been given.
- 4- Convulsions may be controlled with diazepam although CNS depressants need to be avoided.
- 5- Supportive and symptomatic treatment may include artificial respiration, external cooling for hyperpyrexia, and intravenous fluids. Vasopressors such as noradrenaline or phenylephrine may be used, but adrenaline must not be given.

PRECAUTIONS FOR H₁ - RECEPTOR ANTAGONISTS (Antihistamines)

- 1- Antihistamines should not be given to premature infants or neonates, since they have increased susceptibility to antimuscarinic effects.
- 2- Elderly patients are also more susceptible.
- 3- Patients on antihistamine treatment should not drive or operate machinery. They should avoid alcoholic drinks.
- 4- Antihistamines should be used with precaution in closed-angle glaucoma, urinary retention, prostatic hypertrophy, or pyloroduodenal obstruction.
- 5- Patients with epilepsy, severe cardiovascular disorders, liver disorders should use antihistamines with caution.
- 6- Patients with asthma need to be cautious.
- 7- Pro and con studies to the use of antihistamines during pregnancy, have been published.

INTERACTIONS OF ANTIHISTAMINES

- 1- Antihistamine may enhance the sedative effects of CNS depressants: alcohol, barbiturates, hypnotics, opioid analgesics, anxiolytic sedatives and neuroleptics.
- 2- MAOI may enhance the antimuscarinic effects of antihistamines; the latter have an additive antimuscarinic action with other antimuscarinic drugs like atropine and tricyclic antidepressants.
- 3- Antihistamines may suppress positive skill test results and should be stopped several days before the test.

VITAMIN ADMINISTRATION ADVERSE EFFECTS / PRECAUTIONS TO BE TAKEN

Adverse effects due to vitamins in Cypro-Vita® are practically non-existent.

- 1- Hypersensitivity reactions have occurred with Thiamine mainly after parenteral administration.
- 2- Riboflavin has no adverse effects.
- 3- Vitamin B₁₂ in doses of greater than 10µg daily may produce a haematological response in patients with folate deficiency (folic acid salt). Allergic hypersensitivity reactions have occurred rarely.
- 4- Ascorbic acid is usually well tolerated. Large doses of Vitamin C are reported to cause diarrhea and other gastro-intestinal disturbances. Large doses may also result in hyperoxaluria and the formation of renal calcium oxalate calculi. Tolerance may be induced with prolonged use of large doses.
- 5- Excessive amounts of Vitamin A, over long periods can lead to toxicity (more than 10 tablets) manifested by fatigue, irritability and loss of weight, skin changes, dry hair, anemia, headache.

Pregnant women need to be cautious about Vitamin A intake of large doses, since it might cause birth defects.

STORAGE CONDITIONS

Store in a dry place below 30°C, protected from light. Do not refrigerate.

Do not use after expiry date.

PRESENTATION

Cypro-Vita® tablets are supplied in packages of 30 tablets.

This is a medicament

- A Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children

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