Tres-Orix Forte®

Liquid

Highnoon

COMPOSITION
Each 5ml contains:
Cyproheptadine Orotate 1.5mg
Carnitine Hydrochloride 150mg
Lysine Hydrochloride 150mg
Vitamin B_1 10mg
Vitamin B_6 10mg
Vitamin B_{12} 100mcg
Excipient q.s.

DESCRIPTION
Tres-orix FORTE is a combination of appetite simulant, amino acids, multivitamins.

MECHANISM OF ACTION & USAGE
Cyproheptadine is a histamine antagonist with antimuscarinic, serotonin antagonist, calcium channel blocking action and a possible appetite-stimulating effect. The probable mechanisms for appetite-stimulating effect of this drug including constant increased energy intake through more desire to eating and stimulation of growth hormone secretion by deep sleep induction. Cyproheptadine appears to be a safe, generally well-tolerated medication that has utility in helping facilitate weight gain in patients drawn from a variety of underweight populations.

Carnitine, derived from an amino acid, is found in nearly all cells of the body. Carnitine plays a critical role in energy production. It transports long-chain fatty acids into the mitochondria so they can be oxidized to produce energy. It also transports the toxic compounds generated out of this cellular organelle to prevent their accumulation. Given these key functions, carnitine is concentrated in tissues like skeletal and cardiac muscle that utilize fatty acids as a dietary fuel

Lysine is an essential amino acid that cannot be made by the body and used as a dietary supplement. It is important for building protein. Lysine is important for proper growth, and it plays an essential role in the production of carnitine, a nutrient responsible for converting fatty acids into energy and helping lower cholesterol. Lysine appears to help the body absorb calcium, and it plays an important role in the formation of collagen, a substance important for bones and connective tissues including skin, tendons, and cartilage.

Vitamin B_1 also known as thiamine is a water-soluble vitamin found naturally in some foods, added to foods, and sold as a supplement. Thiamine plays a vital role in the growth and function of various cells. It helps the body convert carbohydrates into glucose, which the body uses to produce energy.

Only small amounts are stored in the liver, so a daily intake of Thiamine -rich foods is needed. Because Thiamine is involved in several basic cell functions and the breakdown of nutrients for energy, a deficiency can led to various problems in the brain and heart that require a constant supply of energy. Thiamine deficiency can lead to beriberi, a medical condition which may cause muscle loss and diminished feeling in the hands and feet (peripheral neuropathy).

Pyridoxine is a vitamin soluble vitamin needed to help make neurotransmitters. These include gamma-aminobutyric acid (GABA), epinephrine, norepinephrine, dopamine, and serotonin. It assists to perform various functions, including the breakdown of proteins, carbohydrates, and fats; maintaining normal levels of homocysteine (since high levels can cause heart problems); and supporting immune function and brain health.
This vitamin is needed to help convert stored energy (glycogen) to blood sugar (glucose). Low levels of pyridoxine can lead to numbness or tingling in the hands and feet (peripheral neuropathy) and seizures. This vitamin is needed for red blood cells to form. It's needed for iron to convert into haemoglobin. Low levels of pyridoxine can cause anaemia and many other health problems.

Vitamin B_{12} (cobalamin) plays an essential role in red blood cell formation, cell metabolism, nerve function and the production of DNA, the molecules inside cells that carry genetic information. Vitamin B_{12} is required for the development, myelination, and function of the central nervous system and DNA synthesis. Vitamin B_{12} functions as a cofactor for two enzymes, methionine synthase and L-methyl malonyl-CoA mutase. Methionine synthase catalyses the conversion of homocysteine to the essential amino acid methionine. Vitamin B_{12} deficiency can lead to anaemia, fatigue, muscle weakness, intestinal problems, nerve damage and mood disturbances.

PHARMACOKINETICS
Most (54–86%) dietary carnitine is absorbed in the small intestine and enters the bloodstream. The kidneys efficiently conserve carnitine, so even carnitine-poor diets have little impact on the body's total carnitine content. Rather than being metabolized, excess carnitine is excreted in the urine as needed via the kidneys to maintain stable blood concentrations.
Ingested thiamine from food and dietary supplements is absorbed by the small intestine through active transport at nutritional doses and by passive diffusion at pharmacologic doses. Most dietary thiamine is in phosphorylated forms, and intestinal phosphatases hydrolyse them to free thiamine before the vitamin is absorbed. The remaining dietary thiamine is in free (absorbable) form. Humans store thiamine primarily in the liver, but in very small amounts. The vitamin has a short half-life, so people require a continuous supply of it from the diet.
About 80% of the approximately 25–30 mg of thiamine in the adult human body is in the form of thiamine diphosphate (TDP; also known as thiamine pyrophosphate), the main metabolically active form of thiamine. Bacteria in the large intestine also synthesize free thiamine and TDP, but their contribution, if any, to thiamine nutrition is currently unknown. TDP serves as an essential cofactor for five enzymes involved in glucose, amino acid, and lipid metabolism.
The human body absorbs vitamin B_6 in the jejunum. Phosphorylated forms of the vitamin are dephosphorylated, and the pool of free vitamin B_6 is absorbed by passive diffusion.
Vitamin B_6 concentrations can be measured directly by assessing concentrations of Pyridoxal 5' phosphate; other vitamers; or total vitamin B_6 in plasma, erythrocytes, or urine. Vitamin B_6 concentrations can also be measured indirectly by assessing either erythrocyte aminotransferase saturation by Pyridoxal 5' phosphate or tryptophan metabolites. Plasma Pyridoxal 5' phosphate is the most common measure of vitamin B_6 status.
Vitamin B_{12} is bound to protein in food and must be released before it is absorbed. The process starts in the mouth when food is mixed with saliva. The freed vitamin B_{12} then binds with haptocorrin, a cobalamin-binding protein in the saliva. More vitamin B_{12} is released from its food matrix by the activity of hydrochloric acid and gastric protease in the stomach, where it then binds to haptocorrin. In the duodenum, digestive enzymes free the vitamin B_{12} from haptocorrin, and this freed vitamin B_{12} combines with intrinsic factor, a transport and delivery binding protein secreted by the stomach's parietal cells. The resulting complex is absorbed in the distal ileum by receptor-mediated endocytosis. If vitamin B_{12} is added to fortified foods and dietary supplements, it is already in free form and therefore does not require the separation step.

DOSAGE AND ADMINISTRATION
Adults: 1 tablespoonful twice daily before meals.
Children
Infants: 2 teaspoonful of 2.5ml twice daily,
From 2 to 6 years old: 2 teaspoonful of 5ml twice daily,
From 7 to 12 years old: 1 teaspoon of 5ml thrice daily.
The appearance of drowsiness is a good sign for calculating the dosage and is even desirable to appear slightly in nervous children, as their psychic condition improves simultaneously. However, drowsiness tends to disappear a few days after beginning of treatment. The effects of treatment are usually observed between 4 to 10 days after administration is initiated. Treatment can be administered for periods of one two months with rest periods of 15 days to one month, without any undesirable side effects having been noticed or any alteration of the humoral constants.

CONTRAINDICATIONS

- Hypersensitivity to its components
- Angle closure Glaucoma
- Predisposition to urine retention
- Newborns
- It should not be administered simultaneously with other medicines which are Central Nervous System depressants.
- Hypersensitivity to cyproheptadine and other drugs of similar chemical structure.
- Monoamine oxidase inhibitor therapy
- Stenosing peptic ulcer
- Symptomatic prostatic hypertrophy
- Bladder neck obstruction
- Pyloroduodenal obstruction
- Elderly, debilitated patients

ADVERSE REACTIONS
The common adverse events are; dry mouth, nose, drowsiness, dizziness, nausea, chest congestion, headache, muscle weakness, difficulty urinating, vision problems, nervousness, anaemia, fatigue, muscle weakness, intestinal problems, nerve damage, mood disturbances.

DRUG INTERACTIONS
- *Cyproheptadine:* MAO inhibitors prolong and intensify the anticholinergic effects of antihistamines. Antihistamines may have additive effects with alcohol and other CNS depressants, e.g., hypnotics, sedatives, tranquilizers, antianxiety agents.
- Vitamin B_{12} has the potential to interact with certain medications. In addition, several types of medications might adversely affect vitamin B_{12} levels. A few examples are provided below. Individuals taking these and other medications on a regular basis should discuss their vitamin B_{12} status with their healthcare providers.
- *Gastric acid inhibitors:* Gastric acid inhibitors include proton pump inhibitors, such as omeprazole and lansoprazole, and histamine 2-receptor antagonists, such as cimetidine and ranitidine. These drugs are used to treat gastroesophageal reflux disease and peptic ulcer disease. They can interfere with vitamin B_{12} absorption from food by slowing the release of gastric acid into the stomach and thereby lead to vitamin B_{12} deficiency.
- *Metformin:* an antihyperglycemic agent used as first-line treatment for prediabetes and diabetes, might reduce the absorption of vitamin B_{12} and significantly reduce serum vitamin B_{12} concentrations.
- Arginine and lysine share common pathways in the body. High levels of arginine may lower lysine levels in the body.
- Aminoglycoside antibiotics (gentamicin, neomycin, streptomycin, etc.): Use with lysine may increase the risk of nephrotoxicity.

WARNINGS AND PRECAUTIONS
- Development of dependence has been reported with Cyproheptadine. 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
- It contains ethanol as excipient, which can be cause of risk in patients with hepatic disease, alcoholism, epilepsy and in pregnant women and children.
- 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.
- Drug Interactions: MAO inhibitors prolong and intensify the anticholinergic effects of antihistamines. Antihistamines may have additive effects with alcohol and other CNS depressants, e.g., hypnotics, sedatives, tranquilizers, antianxiety agents.

USE IN SPECIAL POPULATION
Pregnancy: Cyproheptadine should be used during pregnancy only if clearly needed. Nursing Mothers: 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.
Breast Feeding
It is contraindicated in the breast feeding.
Podiatric Use: Safety and effectiveness in podiatric patients below the age of two have not been established.
Geriatric Use: In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

DOSAGE AND INSTRUCTIONS
To be sold and used on the prescription of a registered medical practitioner only. Keep out of reach of children. Do not store above 30ºC. Keep in dry place. Protect from light.

Detailed prescribing information is available at
www.highnoon-labs.com

PRESENTATION
Tres-orix FORTE Liquid: Glass amber bottle of 120ml.

ٹریس-اوریکس
فورٹ®
لیکوئیڈ

خوراک و ہدایات:
صرف مستند ڈاکٹر کے نسخہ کے مطابق ہی دوا فروخت اور استعمال کی جائے۔
بچوں کی پہنچ سے دور رکھیں۔ 30°C سے زیادہ درجہ حرارت پر نہ رکھیں۔
خشک جگہ پر رکھیں۔ روشنی سے بچائیں۔

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HIGHNOON LABORATORIES LTD
17.5 KM, Multan Road, Lahore, Pakistan.
www.highnoon-labs.com

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