

PROFESSIONAL INFORMATION

Category D: Complementary Medicine

Health supplements: 34:12 Multiple substance formulation

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS: **S0**

1. NAME OF THE MEDICINE:

VITA-THION GRANULES

Strength

Ascorbic Acid (Vitamin C)	500,00 mg
Calcium Inositol Hexaphosphate providing Calcium	100,00 mg 27,07 mg
providing Phosphorus	20,92 mg
Thiamine Hydrochloride (Vitamin B ₁)	1,57 mg
Glutathione	0,50 mg
Sodium Adenosine Triphosphate (Disodium Dihydrate) providing Adenosine Triphosphate	0,50 mg 0,43 mg
providing Phosphorus	0,08 mg
Total phosphorus	21,00 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each 5 g contains:

Ascorbic Acid (Vitamin C)	500,00 mg
Calcium Inositol Hexaphosphate providing Calcium	100,00 mg 27,07 mg
providing Phosphorus	20,92 mg
Thiamine Hydrochloride (Vitamin B ₁)	1,57 mg
Glutathione	0,50 mg
Sodium Adenosine Triphosphate (Disodium Dihydrate) providing Adenosine Triphosphate	0,50 mg 0,43 mg
providing Phosphorus	0,08 mg
Total phosphorus	21,00 mg

Contains sugars (Sucrose 2,82 g and Lactose monohydrate 0,60 g)

For a full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Granules. Pink to red and white granules.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications:

- Helps to metabolise carbohydrates, fats and proteins.
- Contributes to normal energy-yielding metabolism.
- Contributes to the normal function of the heart.
- Contributes to iron absorption from food.
- Contributes to maintain the normal function of the immune system during and after intense physical stress.
- Helps in the development and maintenance of bones, cartilage, teeth and gums.
- Helps in connective tissue formation.
- Helps in wound healing.
- Contributes to the reduction of tiredness and fatigue.
- Contributes to the normal function of the immune system.
- Source of antioxidants.
- Assists in increasing physical energy.

4.2 Posology and method of administration

Adults: 1 to 2 sachets dissolved in water at breakfast.

Children: 2 to 5 years: half (½) a sachet at breakfast.

5 to 15 years: half (½) a sachet at breakfast and half (½) a sachet at lunch.

Do not exceed the recommended dose. Method of administration: Sachet is to be dissolved in water.

4.3 Contraindications:

- Known hypersensitivity to the active substance or to any of the excipients listed under section 6.1.
- Large doses of vitamin C may result in hyperoxaluria and formation of renal calcium oxalate calculi.
- Large amounts of Vitamin C can cause haemolysis in patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency.
- Larger amounts of vitamin C can increase the risk of oxalate kidney stones in patients prone to oxalate stone formation.
- Vitamin C may increase the absorption of iron in iron-deficiency states.
- Alcoholism increases the risk of vitamin B₁ deficiency.
- Chronic liver disease, especially cirrhosis, increases the risk of Vitamin B₁ deficiency, regardless of alcohol use.
- Adenosine triphosphate (ATP) can cause hyperuricemia and uricosuria, and might precipitate gout.
- ATP can cause cardiac ischaemia and chest pain. It might worsen symptoms in patients with heart diseases such as angina and myocardial infarction.

4.4 Special warnings and precautions for use

- Tolerance may be induced with prolonged use of large doses, resulting in symptoms of deficiency when intake is reduced to normal.
- Inositol has antiplatelet effects and might cause excessive bleeding if used perioperatively. Tell patients to discontinue inositol at least 2 weeks before elective surgical procedure.
- Patients receiving haemodialysis seem to be at risk for Vitamin B₁ deficiency. Vitamin B₁ supplementation may be needed in these patients.
- Consult a relevant health care provider before use if pregnant, intending to become pregnant or breastfeeding.
- Patients with the rare hereditary condition such as fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take VITA-THION GRANULES.
- Patients with the rare hereditary condition of galactose intolerance e.g., galactosaemia, Lapp lactase deficiency, glucose-galactose mal-absorption or fructose intolerance should not take VITA-THION GRANULES.
- VITA-THION GRANULES contains sucrose and lactose monohydrate which may have an effect on the glycaemic control of patients with diabetes mellitus.

4.5 Interaction with other medicines and other forms of interaction

Interactions with medicines

Alkylating agents/Antitumour antibiotics: The antioxidant effects of vitamin C might reduce the effectiveness of these medicines.

Aluminium: Vitamin C can increase the amount of aluminium absorbed from aluminium compounds.

Antigout medicines (allopurinol, colchicine & probenecid): ATP can cause hyperuricemia and uricosuria, and might reduce the effectiveness of these medicines.

Calcium, Iron and Zinc: Concurrent use of with inositol may decrease mineral absorption.

Carbamazepine: Concomitant use with ATP might have an additive effect on heart block.

Dipyridamole: Dipyridamole decreases the metabolism of ATP and can increase its pharmacologic and toxic effects.

Estrogens: Vitamin C increases estrogen levels in plasma when taken concurrently with oral contraceptives or hormone replacement therapy, including topical products.

Fluphenazine: Vitamin C might decrease levels of fluphenazine.

Indinavir: Vitamin C can modestly reduce indinavir levels.

Levothyroxine: Vitamin C can increase levothyroxine absorption.

Omeprazole: Omeprazole may affect the bioavailability of dietary vitamin C.

Warfarin: High dose Vitamin C might reduce the levels and effectiveness of warfarin.

Nutrient depletion:

Nutrient	Medicine/ substance
Vitamin C	Aspirin, Diuretic drugs, Estrogens, Proton Pump Inhibitors (PPI), Alcohol and Calcium Channel Blockers.
Vitamin B1	Antibiotics drugs, Contraceptive drugs, Diuretic drugs, 5- Fluorouracil, Metformin and Phenytoin.
Glutathione	Paracetamol and Alcohol.

Interactions with food & alcohol

Caffeine-Containing Foods: Caffeine might decrease the effectiveness of ATP since caffeine and other

methylxanthines are competitive antagonists for adenosine receptors.

Betel nut: Chronic, regular chewing of betel nuts may increase the risk of Vitamin B₁ deficiency.

Interaction with laboratory tests

Vitamin C, a strong reducing agent, interferes with laboratory tests involving oxidation and reduction reactions.

Large amounts of thiamine can interfere with Schack and Waxler spectrophotometric determination of serum theophylline concentrations.

Thiamine can cause false positive results in the phosphotungstate method for uric acid determination.

Thiamine can cause false positive results in the urine spot test with Ehrlich's reagent for urobilinogen.

ATP can interfere with electrocardiogram tests results, which can indicate cardiac ischaemia.

4.6 Fertility, pregnancy and lactation

Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

Breastfeeding

Vitamin C is excreted into breast milk and thus supplied to breast-fed infants.

Fertility

No fertility data available.

4.7 Effects on ability to drive and use of machines

VITA-THION GRANULES has no known influence on the effects of driving and the use of machinery.

4.8 Undesirable effects

System organ class	Frequency	Undesirable effects
Gastrointestinal disorders	Common	Oesophagitis, nausea, vomiting, heartburn, abdominal cramps, gastrointestinal obstruction and diarrhoea.
Neurologic disorders	Unknown	Fatigue, headache, insomnia and sleepiness.
Genitourinary disorders	Unknown	precipitation of urate, oxalate, cysteine stones
Skin disorders	Unknown	Dermatitis
Pulmonary/Respiratory disorders	Unknown	Breathing deeper, chest pressure or chest pains.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. May also report to Adcock Ingram Pharmacovigilance department by email Adcock.AEReports@adcock.com, fax +27 86 553 0128 or call 011 635 0134.

4.9 Overdose

In overdose, side effects can be precipitated and/or be of increased severity. See section 4.8, Undesirable effects.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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Mechanism of action

Vitamin C is a water-soluble vitamin responsible for several physiological functions and metabolic processes.

Inositol is required for cellular signaling.

Vitamin B₁ is a water-soluble B-complex vitamin responsible for carbohydrate metabolism.

Glutathione is involved in DNA synthesis and repair, protein and prostaglandin synthesis, amino acid transport, metabolism of toxins and carcinogens, immune system function, prevention of oxidative cell damage, and enzyme activation.

ATP is responsible for a variety of physiological processes, including cellular metabolism, nucleic acid synthesis, neurotransmission, muscle contraction, cardiac function, platelet function, vasodilation, and liver glycogen metabolism.

5.2 Pharmacokinetic properties

Vitamin C is well absorbed orally at lower doses, but absorption decreases as the dose increases. This is due to the fact that vitamin C is transported from the intestines into the blood by the sodium-dependent vitamin C transporter (SVCT1), which is saturable. Most vitamin C that is absorbed is excreted in the urine.

Dietary and supplemental **inositol** is absorbed by the intestinal mucosa and transported in the plasma. It is most likely metabolized in the gut to inositol prior to absorption.

Vitamin B₁ is absorbed at the proximal part of the small intestine. It is distributed into the skeletal muscle, the heart, the liver, the kidneys, and the brain. Vitamin B₁ is phosphorylated during intestinal uptake. Most of thiamine in the adult human body occurs as the metabolically active form thiamine diphosphate. Vitamin B₁ and its metabolites are excreted in the urine.

Oral **glutathione** might be inactivated by peptidases in the gut.

ATP is broken down to adenosine diphosphate (ADP), then to AMP, and then to adenosine. Following the digestive process, adenosine and inorganic phosphate are absorbed in the small intestine and enter the portal circulation and are incorporated into the liver ATP pools.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Colour Ponceau Red 4R 124 [E124]
- Dry orange extract
- Lactose monohydrate
- Polysorbate 80 [E433]
- Potassium Hydrogen tartrate
- Sodium alginate [E401]
- Sodium bicarbonate [E500]
- Sodium chloride
- Sucrose
- Tartaric acid [E334]
- Tragacanth [E413]

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store at or below 25 °C in a dry place.

6.5 Nature and contents of container

Boxes containing 2, 10, 20, 30 and 60 sachets of a paper Polyethylene- Aluminium- Polyethylene complex.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION:

Adcock Ingram Limited
1 New Road, Erand Gardens, Midrand, 1685
Customer Care: 0860 ADCOCK / 232625

8. REGISTRATION NUMBER:

To be allocated

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be allocated.

10. DATE OF REVISION OF THE TEXT:

To be allocated.