PROFESSIONAL INFORMATION
Complementary Medicine, Health Supplement
This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use
SCHEDULING STATUS: S0
NAME OF THE MEDICINE: ALPHA ImmuneBOOST Effervescent Tablets 10's and 30's
QUALITATIVE AND QUANTITATIVE COMPOSITION
• ACTIVE INGREDIENTS:
Each effervescent tablet contains: mg/IU *%NRV
Vitamin A (Palmitate) 250000iU/g
providing all-trans retinol
16mg/4000iU
1200 mcg
133
Vitamin C (Ascorbic acid) 1000 mg 1000
Vitamin D3 100 000 iU
Providing cholecalciferol (elemental)
4mg
10 mcg
66
Alpha Tocopherol (Vitamin E) providing alpha-tocopherol (elemental)
89.4mg
44,7 mgTE
298
Magnesium AAC 20%
providing magnesium (elemental)
200mg
40 mg
10.5
Manganese AAC 10%
providing manganese (elemental)
30mg
3 mg
130
Potassium chloride
providing potassium (elemental)
147mg
77.09 mg
**
Selenium AAC 2%
providing selenium (elemental)
0.8mg
16 µg
29
Tri Sodium citrate
providing sodium (elemental)
129mg
34.48 mg
**
Zinc AAC 10%
providing zinc (elemental)
40mg
4 mg
36
Echinacea purpurea (Echinacea) Leaf
As 140mg of a 4:1 extract
140 mg **
Zingiber officinalis (Ginger Root extract)
As 50mg of a 4:1 extract
50 mg ** L-Glutamine 25 mg **
L-Lysine 25 mg **
*NRV (Nutrient Reference Values)
** No NRV established
• Contains Sugars: Mannitol 374 mg per effervescent tablet
• Contains Sweeteners: Sucralose 25 mg per effervescent tablet
• Excipients: Sunset Yellow (E110) (5 mg), Orange Flavouring (200 mg) and a proprietary effervescent blend (2278 mg).
• Effervescent blend: sodium bicarbonate, citric acid, polyethylene glycol and silicon dioxide.
PHARMACEUTICAL FORM
• Effervescent Tablet
• Speckled pale orange, cylindrical.
CLINICAL PARTICULARS
THERAPEUTIC INDICATIONS
ALPHA ImmuneBoost Fizzy may be used as a daily maintenance supplement and may help in the prevention and treatment of:
• Colds and Flu
• Repeated bacterial or viral infections
Posology and Method of Administration
Adults: One effervescent tablet daily dissolved in a glass (250 ml) of water, after a meal.
Children: ALPHA ImmuneBoost Fizzy is not recommended for this age group.
Do not exceed the recommended dosage without consulting a relevant healthcare provider.
CONTRAINDICATIONS
Hypersensitivity to the active substances or to any of the excipients or to members of the Compositae family of plants.
Children. • Sever renal impairment and neuromuscular disease.
• Hypercalcaemia, haemochromatosis, and other iron storage disorders.
• Vitamin A is contraindicated in pregnancy, breastfeeding patients, and patients with hypersensitivity to this class of drugs. It should be prescribed with caution to patients with hepatic disease, renal disease, alcoholism, and acne vulgaris.
• Vitamin C supplementation is contraindicated in blood disorders like thalassemia, G6PD deficiency, sickle cell disease, and hemochromatosis. Avoid taking supplements immediately before or following angioplasty. Diabetic patients should take vitamin C supplements with care as it raises blood sugar levels.
• Vitamin C should be used cautiously in oxalate nephropathy or nephrolithiasis as possible acidification by ascorbic acid may increase the chances of precipitation of cysteine, urate, and oxalate stones.
• Liver Cirrhosis (due to the Manganese content) • Echinacea is contra-indicated in patients suffering from Autoimmune disease,
Diabetes, Systemic Lupus Erythematosus, Rheumatoid Arthritis, Multiple Sclerosis, Leukosis, Tuberculosis and HIV infection.
Consult a registered healthcare provider prior to use if you are taking any other medicine or have been diagnosed with a chronic condition.
See “SPECIAL WARNINGS AND PRECAUSTIONS FOR USE”
SPECIAL WARNINGS AND PRECAUTIONS FOR USE
Consult a registered healthcare provider prior to use if you are taking any other medicine or have been diagnosed with a chronic condition.
Do not exceed the recommended doses.
Certain medications may be influenced by ALPHA ImmuneBOOST Fizzy (see MEDICINE INTERACTIONS). Consider using ALPHA ImmuneBOOST Fizzy two (2) hours before or four (4) hours after such medications.
See “INTERACTIONS”
Consult a relevant healthcare provider if you:
• have severe renal impairment and neuromuscular disease.
• Have Hypercalcaemia, haemochromatosis, and other iron storage disorders.
• are pregnant or breastfeeding
• have hepatic disease, renal disease, alcoholism, or acne vulgaris.
• Patients suffering from glucose-6-phosphatase deficiency should not take higher than the recommended dose as very high doses of Vitamin C may lead to haemolytic anaemia.
See “CONTRAINDICATIONS”
Ascorbic Acid (Vitamin C)
In patients suffering from renal failure or insufficiency, acute or chronic high doses of Ascorbic Acid increases risk of adverse effects including acute tubular necrosis, and/or renal failure.
Vitamin C may interfere with laboratory tests resulting in false readings. If such tests are planned, discontinue use of ALPHA ImmuneBOOST Fizzy 3-4 days prior to the test and resume after completion.
Vitamin C may interfere with test kits and meters measuring glucose levels resulting in false results. Please check the package insert of the test kit or meter for guidance.
INTERACTIONS
Medicine interactions
The efficacy of certain medicines may be affected by the presence of nutrients.
Echinacea
Interactions between medications and Echinacea are not uncommon. While the dosage present in ALPHA ImmuneBOOST Fizzy is not known to cause significant interactions, it should nevertheless be introduced with caution in patients consuming acute or chronic medication.
Echinacea may cause unwanted side effects when used with:
• Echinacea may interact with immunosuppressants. • Rasagiline (Azilect) an MOA-type B inhibitor due to Echinacea's inhibition of the
CYP450 1A2 isoenzyme (conflicting data). If symptoms such as drowsiness, blood pressure changes, nausea, vomiting, or behavioural changes occur, discontinue use of ALPHA ImmuneBOOST Fizzy
• Tizanidine (Zanaflex) an anti-spasmodic due to Echinacea's inhibition of the CYP450 1A2 isoenzyme (conflicting data). If symptoms such as drowsiness, dizziness, light headedness, hypotension, and bradycardia occur, discontinue use of ALPHA ImmuneBOOST Fizzy.
Vitamin C
Vitamin C may reduce cyclosporine (immunosuppressant) blood levels.
High doses of vitamin C may reduce the serum concentration of Indinavir (antiretroviral), which may interfere with the effectiveness of Indinavir.
Chronic or high doses of Vitamin C may interfere with the effectiveness of Disulfiram.
High doses of Vitamin C may interfere with the effectiveness of Warfarin
The absorption of Vitamin C from the intestinal tract may be negatively affected by a very wide range of pharmaceuticals.
Vitamin A
Many medications such as aspirin, antibiotics, laxatives, antacids, Cholestyramine and Neomycin may inhibit the absorption of Vitamin A from the intestinal tract.
Vitamin E
At levels of >400iU per day, Vitamin E may influence the efficacy of certain anti-coagulants. In patients using additional sources of Vitamin E, it is therefore advisable to monitor coagulation levels when commencing use of ALPHA ImmuneBOOST Fizzy.
Ginger
It was previously believed that Ginger may influence the efficacy of Warfarin. While this has been disproven, it is nevertheless advisable to monitor coagulation levels in patients using Warfarin when commencing use of ALPHA ImmuneBOOST Fizzy. Other medications which may interact with ginger, albeit usually at higher doses, include agents with antiplatelet properties, non-steroidal anti-inflammatory agents, salicylates or thrombolytic agents, anti hypertensives, and hypoglycaemic agents.
Zinc
Zinc forms complexes with certain substances in the intestine (including tetracyclines, quinolone antibiotics and penicillamine) resulting in decreased absorption of both Zinc and the medication. This may typically be prevented by separating the consumption of ALPHA ImmuneBOOST Fizzy by two (2) hours before or four (4) hours after use of the other drug, unless otherwise specified.
Minerals
The acute or chronic use of antacids may lead to malabsorption of some minerals (due to the calcium content of many antacids) and the resulting imbalances and deficiencies.
Food Interactions
Vitamin C
Ascorbic Acid may increase absorption of Iron from the intestine.
• This may be of particular benefit to patients with iron deficiency.
• In patients with homo- or heterozygous hereditary hemochromatosis small increases in iron absorption may lead to iron overload.
Minerals
Dairy products used at the same time as ALPHA ImmuneBOOST Fizzy may inhibit the absorption of minerals from the intestine due to the Calcium content of dairy products.
Other Interactions
Vitamin C and laboratory tests
Vitamin C is a strong reducing agent. It can therefore influence laboratory tests based on oxidation-reduction reactions, such as the urine or serum analyses of glucose, creatinine, carbamazepine, uric acid, and inorganic phosphates or the analysis of occult blood in faeces. Using specific tests that are not dependent on reducing properties or discontinuing extra dietary vitamin C a few days prior to the tests will avoid any undesirable interference. Refer to the manufacturer’s information to determine if vitamin C interferes with the test.
Although Vitamin C has no effect on blood glucose levels, it may affect the readings of home tests that measure urinary and blood glucose, resulting in false readings. Please refer to the package insert of the meter or testing kit for correct usage.
FERTILITY, PREGNANCY AND LACTATION
ALPHA ImmuneBOOST Fizzy has not been tested for safety during Pregnancy and Lactation. No fertility data available.
EFFECTS ON ABILITY TO DRIVE AND USE MACHINES
ALPHA ImmuneBOOST Fizzy has no or negligible influence on the ability to drive and use machines.
UNDESIRABLE EFFECTS
ALPHA ImmuneBOOST Fizzy may have some side-effects although none have been reported to date and ALPHA ImmuneBOOST Fizzy is generally well tolerated.
If symptoms arise, discontinue use.
Undesirable effects are listed by MedDRA System Organ Classes.
Assessment of undesirable effects is based on the following frequency groupings:
Very common (≥1/10); common (≥1/100 to 1/10); uncommon (≥1/1 000 to 1/100); rare (≥1/10 000 to 1/1 000); very rare (1/10 000); Not known; cannot be estimated from the available data
Immune system disorder
Frequency not known
Hypersensitivity
Gastrointestinal disorder
Frequency not known
Minor gastrointestinal complaints, particularly stomach upset, eructation, dyspepsia and nausea have been reported.
Excessive Vitamin C may cause diarrhoea. If other sources of Vitamin C are being used, consider reducing the total daily intake, or spreading the intake out in smaller doses throughout the day.
Renal and urinary disorder
Frequency not known
Renal impairment, mild increase in urine creatinine.
Musculoskeletal and connective tissue disorder
Frequency not known
Muscle cramps
Skin and subcutaneous tissue disorders
Frequency not known
Hypersensitivity reactions (Skin rash)
Nervous system disorders
Frequency not known
Headache, changes in vision.
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
OVERDOSE
Vitamin A
Excess natural or synthetic vitamin A levels may result in a wide array of adverse effects. Vitamin A toxicity, also known as hypervitaminosis A, is more commonly associated with abuse of vitamin A supplements than with health intervention programs. Toxic reactions may also be provoked by consuming liver products rich in vitamin A or excess administration of vitamin A preparations. The amount of vitamin A required to cause toxicity among individuals varies depending on age and hepatic function.
Acute vitamin A toxicity may occur with a single ingestion of 25,000 IU/kg or more. Signs and symptoms include nausea, vomiting, diarrhea, dizziness, lethargy, drowsiness, increased intracranial pressure, and skin changes such as erythema, pruritus, or desquamation.
Chronic vitamin A toxicity may occur with excessive ingestion of 4000 IU/kg or more daily for 6-15 months. Signs and symptoms include low-grade fever, headache, fatigue, anorexia, intestinal disturbances, hepatosplenomegaly, anemia, hypercalcemia, subcutaneous swelling, nocturia, joint and bone pain, and skin changes such as yellowing, dryness, alopecia, and photosensitivity.
Vitamin C
Individuals with mild to moderate renal insufficiency may be susceptible to some effects of vitamin C toxicity at the levels present and should consult a registered healthcare professional before use of ALPHA ImmuneBOOST Fizzy. These may include elevated serum and urinary oxalate levels. In some instances, this may lead to hyperoxaluria, calcium oxalate crystalluria, calcium oxalate deposition, kidney stone formation, tubulointerstitial nephropathy, and acute renal failure. If symptoms occur, discontinue usage.
It is extremely unlikely that overdose of any other ingredients of ALPHA ImmuneBOOST may occur at the levels present.
See “UNDESIRABLE AFFECTS”
PHARMACOLOGICAL PROPERTIES
Category D: Complementary Medicine
Discipline: Health Supplement
Classification: 34.12 Multiple substance formulation
Pharmacodynamic properties
Vitamin C
Ascorbic acid is an essential water-soluble vitamin and antioxidant. Ascorbic acid and its metabolite dehydroascorbic acid form a reversible redox system. Ascorbic acid functions as a cofactor in several hydroxylation and amination reactions by transferring electrons to enzymes. The antioxidant properties of Ascorbic Acid are largely responsible for its ability to combat pathogens as well as toxins and to bind to waste products of metabolism and infectious processes.
Vitamin A
Vitamin A is a fat-soluble vitamin needed for visual adaptation to darkness, maintenance of epithelial cells, immune function, and embryonic development.
Vitamin D
The in vivo synthesis of the biologically active metabolites of vitamin D occurs in two steps. The first hydroxylation of vitamin D3 cholecalciferol occurs in the liver in the presence of Cytochrome P-450 enzymes to yield 25(OH)D3 while the second hydroxylation happens in the kidneys to give 1, 25-dihydroxyvitamin D. This synthesis takes approximately 10 to 24 hours to occur. The Vitamin D metabolism in the kidneys is regulated by parathyroid hormone.
Vitamin E
Vitamin E is a fat-soluble vitamin which acts as an antioxidant to prevent the oxidation of vitamins A and C and polyunsaturated fatty acids in membranes (thereby protecting body cells against free radical damage). It also protects red blood cells against haemolysis.
One mechanism of vitamin E's antioxidant effect is that it reacts with unstable lipid radicals, producing stable lipids and a relatively stable vitamin E radical. The vitamin E radical is then reduced back to stable vitamin E by reaction with ascorbate (Vitamin C) or glutathione.
Echinacea
Biologically active constituents include alkamides (mostly isobutylamides), polyalkenes, polyalkynes, caffeic acid derivatives, and polysaccharides. Studies indicate that the alkamides are available following oral administration, but the caffeic acid derivatives are not.
Manganese
Manganese is an essential nutrient which serves as an activator for enzymes such as polysaccharide polymerase, liver arginase, cholinesterase, and pyruvate carboxylase.
Magnesium
Magnesium is a cofactor for more than 300 enzymes. Several biochemical processes are regulated by Magnesium including blood pressure, nerve transmission, neuromuscular conduction (including cardiac excitability) and vasomotor tone, muscular contraction, and insulin metabolism. Deficiency can impact the nervous, cardiovascular, gastric, or musculo skeletal systems. Magnesium deficiency also impacts the immune system through reduced efficiency of Macrophages and increased incidence of inflammation as well as the optimal development of the thymus and the spleen.
Potassium
Potassium is the major cation of intracellular fluid and is essential for the conduction of nerve impulses in heart, brain, and skeletal muscle; contraction of cardiac, skeletal, and smooth muscles; maintenance of normal renal function, acid-base balance, carbohydrate metabolism, and gastric secretion
Selenium
Selenium is a trace metal which is first metabolized to selenophosphate and selenocysteine and is then incorporated into many different selenoproteins. It is particularly important as a component of glutathione peroxidase and thioredoxin reductase which are enzymes that prevent cellular damage by free radicals and reactive oxygen species. The importance of selenium in these antioxidant proteins is specifically related to the reduction of atherosclerosis by preventing the oxidation of low-density lipoprotein (LDL).
Sodium
Sodium is one of the body’s primary electrolytes and plays an important role in maintaining the hydration homeostasis. 60% of the body's stored Sodium is in the fluids surrounding the Cells (extracellular) and 10% concentrates inside the body's Cells (in the Intracellular Fluid). Sodium is the principal anion (negatively charged ion) in the Intracellular Fluid and may reverse Acidosis.
Zinc
Zinc has three primary biological roles: catalytic, structural, and regulatory. It has been estimated that 10% of human proteins may bind zinc and hundreds more may transport it. It is required for the catalytic activity of more than 200 enzymes, and it plays a role in immune function wound healing, protein synthesis, DNA synthesis, and cell division. Zinc is an essential element for a proper sense of taste and smell and supports normal growth and development during pregnancy, childhood, and adolescence.
L-Glutamine
Glutamine is a non-essential but important constituent of proteins. Glutamine is also crucial in nitrogen metabolism. Ammonia is assimilated into organic compounds by converting glutamic acid to glutamine by the enzyme glutamine synthetase. Glutamine can then be used as a nitrogen donor in the biosynthesis of many compounds, including other amino acids, purines, and pyrimidines. L-glutamine plays a major role in protecting the integrity of the gastrointestinal tract and the large intestine.
L-Lysine
Lysine is an essential amino acid which is helps to regulate the adequate absorption of calcium, helps form collagen (bone cartilage & connective tissues) and aids in the production of antibodies, hormones & enzymes.
Pharmacokinetic properties
Vitamin C
Ascorbic Acid is absorbed primarily in the upper part of the small intestine via sodium dependent active transport. Absorption is dependent upon the amount of ascorbic acid taken at one sitting, with the absorbed percentage decreasing with an increased intake. It is therefore advisable to take oral ascorbic acid in small doses spread throughout the day, rather than in one single, larger dose.
The physiological body pool of vitamin C is about 1500 mg. Plasma protein binding of ascorbic acid is approximately 24%.
Ascorbic acid is metabolised via dehydroascorbic acid partly (0.3%) to oxalic acid and other products. When ingested in excessive quantities, however, ascorbic acid is largely excreted in unchanged form in the urine and faeces.
The elimination half-life following an oral dose of 1 g is about 13 hours. Below an oral intake of about 3 g vitamin C per day, the main route of excretion is renal. With doses exceeding 3 g, increasing quantities are excreted unchanged in the faeces.
Vitamin A
Water miscible preparations of Vitamin A are well absorbed in the small intestine while oil preparations take a bit longer. Large oral doses, conditions of fat malabsorption, low protein intake, or hepatic or pancreatic disease reduce oral absorption. Excess Vitamin A is stored in the liver.
Vitamin A is converted to retinol in the small intestine and further metabolized in the liver where it is conjugated with glucuronide. Metabolite excretion takes place via the Faeces or the urine.
Vitamin D
Vitamin D is absorbed via the Ileum of the Small Intestine with other dietary Fats with the aid of Bile.
The half-life of circulating Vitamin D is 1 – 2 days. The whole-body half-life of Vitamin D3 is approximately 62 days.
Vitamin E
Vitamin E is comprised of several different fat-soluble molecules. Absorption of Vitamin E is dependent upon absorption of the fat in which it is dissolved with about 10-40% being absorbed in the small intestine. Some Vitamin E may be stored in the liver. The various molecules undergo beta oxidation and a process mediated by cytochrome P450s and the metabolites are excreted mainly in the urine but may also be excreted via the faeces (bile).
Manganese
Normally around 20 mcg /day of ingested Manganese is retained. Excretion of Manganese occurs mainly through the bile, but it may also be excreted via pancreatic juice, or be returned into the lumen of the small intestine. Urinary excretion of Manganese is negligible
Manganese is bound to the beta-l-globulin transport protein, transmanganin. Manganese is widely distributed but concentrates in the tissues which are rich in mitochondria such as brain, kidney, pancreas, and liver. Assays for Manganese in whole blood result in concentrations ranging from 6 to 12 mcg/l.
Magnesium
Magnesium is absorbed primarily via passive, paracellular absorption in the ileum of the small intestine. The rate of absorption declines with age. Absorption is inversely proportional to the amount consumed and is therefore highest in persons with Hypomagnesemia and in persons consuming NRV values or less.
The elimination half-life of Magnesium is between 41 and 181 days and the large majority is excreted renally. Magnesium does not appear to be metabolised.
Potassium
Potassium chloride is water soluble, with potassium being readily absorbed (on average 90%) primarily from the large intestine. The average human body contains a total of 120 grams of Potassium. Aldosterone (Steroid Hormone) controls the body's retention of Potassium.
Excess Potassium is eliminated from the body via the Urine and Perspiration.
Selenium
Between 35% - 85% of Selenium ingested may be absorbed from the Gastro-Intestinal tract. The major path of excretion is via the urine. The average human body contains a total of 21 mg of Selenium (for a 70 kg person). The approximate normal Blood Plasma concentration of Selenium is 100 - 130 ng per ml.
Sodium
Sodium is a water soluble, alkalising macro-mineral which is easily absorbed from the Gastro-Intestinal tract. The body of a person of average weight contains about 95 grams of Sodium (mainly in the form of Sodium Chloride). Excess of Sodium is excreted via the urine, the faeces and perspiration.
Zinc
Most orally ingested Zinc is absorbed through the Jejunum (up to 40%-90% on an empty stomach). It is transported to the liver via the portal circulation. A fraction of Zinc is extracted by the Liver Cells, and the remaining Zinc is transported to the various cells of the body via the systemic circulation. Approximately 80% of Zinc is transported in the plasma bound to albumin.
The major route of Zinc excretion is via the gastrointestinal tract. Faecal Zinc excretion is comprised of unabsorbed Zinc and Zinc derived from biliary, pancreatic, and gastrointestinal secretions and Zinc from sloughing of mucosal cells.
L-Glutamine
Absorption occurs via an active transport mechanism from the Gastro-Intestinal tract. Orally administered Glutamine supplements effectively increase serum Glutamine levels (a dose of 5 grams of Glutamine may increase serum Glutamine levels by up to 50% within 30 minutes). Glutamine is involved in the formation of glutamate, proteins, nucleotides, and amino acid sugars and excreted via the relevant metabolites.
L-Lysine
Lysine is absorbed from the small intestine by an active transport mechanism and moved to the liver via the hepatic portal system, where it is metabolised. Lysine is rapidly transported to muscle tissue, and within 5 to 7 hours following ingestion is highly concentrated in the muscle. Metabolites are mainly excreted via the urine.
Preclinical safety data
No specific study with this product was done, but the properties of the active ingredients of ALPHA ImmuneBOOST Fizzy are well known.
PHARMACEUTICAL PARTICULARS
List of excipients
• Excipients: Vanilla Flavour (25 mg), Raspberry Flavour (200 mg), Carmosine Colouring (E122) (2.5 mg), Ponceau Colouring (E124) (2,5 mg) and a proprietary effervescent blend (3454 mg).
• The effervescent blend contains sodium bicarbonate, citric acid, polyethylene glycol and Silicon Dioxide.
Incompatibilities
Not applicable
Shelf life
24 Months
Special precautions for storage
Store at or below 25 °C.
Keep the tube tightly closed to protect from moisture.
Use within 30 days of opening.
Nature and contents of container
10 effervescent tablets in polypropylene tube closed by a PE stopper.
Box of one or three tubes containing 10 or 30 tablets.
Special precautions for disposal and other handling.
Not applicable
APPLICANT (CERTIFICATE OF REGISTRATION)
Alpha Pharm Retail Promotions (Pty) Ltd
Suite 5 Village Square, 19A Village Road, Kloof
www.alphapharm.co.za
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