STANVITE® CAPSULE.

(MULTIVITAMINS, MULTI MINERALS AND ANTIOXIDANT CAPSULES)

SUBMITTED BY: NALIS PHARMACEUTICALS LTD

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SUMMARY OF PRODUCT CHARACTERISTICS

(SmPC) .

1 NAME OF THE MEDICINAL PRODUCT:

Stanvite Capsule.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:
Vitamin A USP (as Palmitate)……25000 IU
Colecalciferol BP……..200 IU
Thiamine HCl BP……..1 mg
Riboflavin BP……..1 mg
Pyridoxine HCl BP……..1 mg
Cyanocobalamin BP……..1 mg
Nicotinamide BP……10 mg
Folic Acid BP……0.75 mg
Dexpanthenol BP……1 mg
Lysine HCl BP……10 mg
Glutamic Acid BP……25 mg
DL-Methionine BP……..9.2 mg
Zinc Suphate Heptahydrate BP (Eq. to Zinc)……10 mg
Potassium Iodide BP (Eq. to Iodine)……50 mcg
Chromic Chloride USP (Eq. to Elemental Molybdenum)……8 mcg
Sodium Molybdate Dihydrate BP (Eq. to Elemental Molybdenum)….8 mcg
Manganese Sulfate USP (Eq. to Manganese)……0.8 mcg
Calcium BP……..1.25 mg
Sodium Selenate (Eq. to Elemental Selenium)……..10 mcg
Syrup Base……q.s

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral capsule

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Stanvite Capsule is used to provide substances that are not taken in through the diet. It is also used to treat vitamin or mineral deficiencies caused by illness, pregnancy, poor nutrition, digestive disorders, certain medications, and many other conditions.

4.2 Posology and method of administration
For oral administration.

Dosage: Adult and children over 12 years

4.3 Contraindications
Stanvite Capsule is contraindicated in patients with hypersensitivity to any of the active components of this drug. It should be prescribed with caution to patients with hepatic disease, renal disease, alcoholism, and acne vulgaris.

4.4 Special warnings and precautions for use
Do not take this drug if you are allergic to multivitamins or any ingredients contained in this drug.
Keep out of reach of children. In case of overdose, get medical help

4.5 Interaction with other medicinal products
Pyridoxine hydrochloride, a component of Stanvite Capsule may reduce the effectiveness of levodopa.

Many drugs are known to interact with multivitamins and minerals. The interactions are classified into
- major drug interactions
- moderate drug interactions
- minor drug interaction.

Consult your physician or Pharmacist before combining multivitamins with other drugs.

4.6 Pregnancy and lactation
The IOM recommends multivitamins that contain iron, zinc, copper, calcium, folic acid, and vitamins D, C, B6, and B12 (note that iodine is not included) for some groups of pregnant women, such as those with iron-deficiency anemia or poor-quality diets, vegetarians, cigarette smokers, and those who consume alcohol.

Folic acid is a vitamin that every cell in your body needs for healthy growth and development. Taking folic acid before and during early pregnancy can help prevent birth defects of the brain and spine called neural tube defects.
Most mineral supplements (e.g., iron, calcium, copper, chromium, zinc) taken by the mother do not affect breastmilk levels.
Water soluble vitamin supplements (e.g., B vitamins, vitamin C) taken by the mother usually increase breastmilk levels. Breastmilk levels of some water soluble vitamins, such as vitamin C, only increase up to a certain point, then remain steady – even if mom increases her dose.

4.7 Effects on ability to drive and use machines
None expected at recommended doses and duration of therapy.

4.8 Undesirable effects
Stanvite Capsule is usually well-tolerated. However, there may be a few cases of upset stomach and headache.

4.9 Overdose
Overdose symptoms may include stomach pain, vomiting, diarrhea, constipation, loss of appetite, hair loss, peeling skin, tingly feeling in or around your mouth, changes in menstrual periods, weight loss, severe headache, muscle or joint pain, severe back pain, blood in your urine, pale skin, and easy bruising or bleeding.

If overdose is suspected, your doctor should be contacted immediately.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
ATC code: A11AA

Mechanism of action:
Vitamins and minerals are considered essential nutrients—because acting in concert, they perform hundreds of roles in the body. They help shore up bones, heal wounds, and bolster your immune system. They also convert food into energy, and repair cellular damage.

Vitamin A plays an essential role in the function of the retina, the growth and function of epithelial tissue, bone growth, reproduction and embryonic development.
In its biologically active form Colecalciferol (Vitamin D) stimulates intestinal calcium absorption, incorporation of calcium into the osteoid, and release of calcium from bone tissue.
Vitamin B_1 is essential for proper carbohydrate metabolism and plays an essential role in the decarboxylation of alpha keto acids
Riboflavin is essential for the utilisation of energy from food. It is a component of co-enzymes which play an essential role in oxidative/ reductive metabolic reactions. Riboflavin is also necessary for the functioning of pyridoxine and nicotinic acid.
Nicotinamide is an essential component of co-enzymes responsible for proper tissue respiration.

Vitamin B_6 is a constituent of the co-enzymes, pyridoxal pyrophosphate and pyridoxamine phosphate, both of which play an important role in protein metabolism.
Folic acid is an essential cofactor for enzymes involved in DNA and RNA synthesis. More specifically, folic acid is required by the body for the synthesis of purines, pyrimidines, and methionine before incorporation into DNA or protein. Folic acid is the precursor of tetrahydrofolic acid, which is involved as a cofactor for transformylation reactions in the biosynthesis of purines and thymidylates of nucleic acids. Impairment of thymidylate synthesis in patients with folic acid deficiency is thought to account for the defective deoxyribonucleic acid (DNA) synthesis that leads to megaloblast formation and megaloblastic and macrocytic anemias. Folic acid is particularly important during phases of rapid cell division, such as infancy, pregnancy, and erythropoiesis, and plays a protective factor in the development of cancer. As humans are unable to synthesize folic acid endogenously, diet and supplementation is necessary to prevent deficiencies. In order to function properly within the body, folic acid must first be reduced by the enzyme dihydrofolate reductase (DHFR) into the cofactors dihydrofolate (DHF) and tetrahydrofolate (THF). This important pathway, which is required for de novo synthesis of nucleic acids and amino acids, is disrupted by anti-metabolite therapies such as Methotrexate as they function as DHFR inhibitors to prevent DNA synthesis in rapidly dividing cells, and therefore prevent the formation of DHF and THF.
Vitamin B_{12} is a coenzyme involved in the metabolism of every cell of the human body, especially affecting DNA synthesis and regulation, but also fatty acid metabolism and amino acid metabolism
Zinc is component of many metalloenzymes.example: red blood cell carbonic anhydrase, alkaline phosphatase ,alcohol dehydrogenase, carboxy-peptidase, SOD (cytosol), and many enzymes involved in RNA and DNA synthesis, such as DNA and RNA polymerases.
Dexpanthenol is an alcohol derivative of pantothenic acid, a component of the B complex vitamins and an essential component of a normally functioning epithelium. Dexpanthenol is enzymatically cleaved to form pantothenic acid, which is an essential component of Coenzyme A, which acts as a cofactor in many enzymatic reactions that are important for protein metabolism in the epithelium.
Lysine ensures the adequate absorption of calcium; helps form collagen (which makes up bone cartilage & connective tissues); aids in the production of antibodies, hormones & enzymes. Recent studies have shown that Lysine may be effective against herpes by improving the balance of nutrients that reduce viral growth. A deficiency may result in tiredness, inability to concentrate, irritability, bloodshot eyes, retarded growth, hair loss, anemia & reproductive problems

Glutamate activates both ionotropic and metabotropic glutamate receptors. The ionotropic ones being non-NMDA (AMPA and kainate) and NMDA receptors. Free glutamic acid cannot cross the blood-brain barrier in appreciable quantities; instead it is converted into L-glutamine, which the brain uses for fuel and protein synthesis. It is conjectured that glutamate is involved in cognitive functions like learning and memory in the brain.
The mechanism of the possible anti-hepatotoxic activity of L-methionine is not entirely clear. It is thought that metabolism of high doses of acetaminophen in the liver lead to decreased levels of hepatic glutathione and increased oxidative stress. L-methionine is a precursor to L-cysteine. L-cysteine itself may have antioxidant activity. L-cysteine is also a precursor to the antioxidant glutathione. Antioxidant activity of L-methionine and metabolites of L-methionine appear to account for its possible anti-hepatotoxic activity. Recent research suggests that methionine itself has free-radical scavenging activity by virtue of its sulfur, as well as its chelating ability.
Potassium iodide works in the thyroid gland. By inhibiting thyroid hormone synthesis and release, thyroid gland vascularity is reduced, thyroid gland tissue becomes firmer, thyroid cell size is reduced, follicular colloid reaccumulates, and bound iodine levels increase. As a protectant following radiation exposure, KI blocks the uptake of radioactive iodine isotopes by the thyroid gland thereby minimizing the risk of radiation-induced thyroid neoplasms.
Trivalent chromium is part of glucose tolerance factor, an essential activator of insulin-mediated reactions. Chromium helps to maintain normal glucose metabolism and peripheral nerve function. Providing chromium during TPN helps prevent deficiency symptoms including impaired glucose tolerance, ataxia, peripheral neuropathy and a confusional state similar to mild/moderate hepatic encephalopathy.

Manganese is important in the breakdown of amino acids and the production of energy. It activates various enzymes for proper digestion and utilization of foods. Manganese also helps nourish the nerves and brain and is necessary for normal skeletal development.
Calcium plays a pivotal role in the physiology and biochemistry of organisms and the cell. It plays an important role in signal transduction pathways, where it acts as a second messenger, in neurotransmitter release from neurons, contraction of all muscle cell types, and fertilization. Many enzymes require calcium ions as a cofactor, those of the blood-clotting cascade being notable examples. Extracellular calcium is also important for maintaining the potential difference across excitable cell membranes, as well as proper bone formation.
Selenium is an essential trace mineral that plays a critical role in antioxidant actions, anti-inflammatory effects, immune function, and the production of active thyroid hormone [1].
Selenium is a constituent of selenoproteins thus has structural and enzymatic roles. It acts as an antioxidant via the actions of selenoproteins for protection against oxidative stress, and acts as a catayst for the production of active thyroid hormone []. It may also play a role in sperm motility

5.2 Pharmacokinetic properties

Vitamin A is readily absorbed from the normal gastrointestinal tract.

Vitamin D is well absorbed from the gastro-intestinal tract in the presence of bile. It is hydroxylated in the liver to form 25-hydroxycolecalciferol and then undergoes further hydroxylation in the kidney to form the active metabolite 1, 25 dihydroxycolecalciferol (calcitriol). The metabolites circulate in the blood bound to a specific α - globin, Vitamin D and its metabolites are excreted mainly in the bile and faeces.
All the B Vitamins are water soluble vitamins. Quantities in excess of the bodies requirements are excreted either unchanged or as metabolites, mainly in the urine but to a lesser extent also in the faeces.

Small amounts of thiamine are well absorbed from the gastrointestinal tract after oral doses, but the absorption of doses larger than about 5mg is limited. Thiamine is not stored to any appreciable extent in the body and amounts in excess of the body's requirements are excreted in the urine unchanged or as metabolites.
Riboflavin is readily absorbed from the gastrointestinal tract. Although riboflavin is widely distributed to body tissues little is stored in the body.
Riboflavin also crosses the placenta and is distributed into breast milk. It is widely distributed to most body tissues and appears in breast milk.
Riboflavin is excreted in urine, partly as metabolites.
Pyridoxine B_6 (pyridoxal and pyridoxamine) are readily absorbed from the gastrointestinal tract after oral doses and are converted to the active forms pyridoxal phosphate and pyridoxamine phosphate.
Pyridoxine is stored mainly in the liver where there is oxidation to 4-pyridoxic acid. Pyridoxal crosses the placenta and is distributed into breast milk.
As the dose increases, proportionally greater amounts are excreted unchanged in the urine.
Folic acid given therapeutically enters the portal circulation largely unchanged, since it is a poor substrate for reduction by dihydrofolate reductase. It is converted to the metabolically active form 5 methltetrahydrofolate in the plasma and liver.
The principal storage site of folate is the liver; it is also actively concentrated in the cerebrospinal fluid. Folate undergoes enterohepatic circulation.
Folate is distributed into breast milk. Folic acid is removed haemodialysis.
Folate metabolites are eliminated in the urine and folate in excess of body requirements is excreted unchanged in the urine.
Vitamin B_{12} substances bind to intrinsic factor; glycoproteins secreted by the gastric mucosa and are then actively absorbed from the gastrointestinal tract. Absorption is impaired in patients with an absence of intrinsic factor.
Vitamin B_{12} is stored in the liver, excreted in the bile and most of it in the first 8 hours; urinary excretion, however, accounts for only a small fraction in the reduction of total body stores acquired by dietary means. Vitamin B_{12} diffuses across the placenta and also appears in breast milk.
Vitamin B_{12} undergoes extensive enterohepatic recycling; part of a dose is excreted in the urine.
Absorption of zinc from the gastrointestinal tract is incomplete and is reduced in the presence of some dietary constituents such as phytates. Bioavailability of dietary zinc varies widely between different sources, but is about 20 to 30%.
Zinc is distributed throughout the body with the highest concentrations found in muscle, bone, skin, eye and prostatic fluids. It is primarily excreted in the faeces and regulation of faecal losses is important in zinc homoeostasis. Small amounts are lost in urine and perspiration.
Dexpanthenol is soluble in water and alcohol, although insoluble in fats and oil based substances. Dexpanthenol is readily converted to pantothenic acid which is widely distributed into body tissues, mainly as coenzyme A. Highest concentrations are found in the liver, adrenal glands, heart, and kidneys. Dexpanthenol is readily converted to pantothenic acid which is widely distributed into body tissues, mainly as coenzyme A. Milk of nursing mothers receiving a normal diet contains about 2 ug of pantothenic acid per mL. About 70% of an oral dose of pantothenic acid is excreted unchanged in urine and about 30% in feces.
Glutamic acid, methionine and lysine are absorbed from the lumen of the small intestine into the enterocytes. Absorption is efficient and occurs by an active transport mechanism.
Potassium iodide is absorbed into the body the body by the thyroid.
Chromium absorption increases with exercise. Chromium is stored in liver, spleen, soft tissue and bone. Most absorbed chromium is excreted rapidly in the urine, whereas unabsorbed chromium is excreted through feces.
Molybdenum appears to be absorbed via a passive nonmediated process, though where absorption occurs in the intestinal tract is not known. Absorbed molybdenum is widely distributed throughout the body, with the highest concentrations found in the kidneys and liver. Molybdenum is not metabolized; however, it can undergo oxidation and reduction. Molybdenum is primarily excreted in the urine, with lesser amounts excreted in feces.
Manganese is absorbed in the small intestine through an active transport system and, possibly, through diffusion when intakes are high. After absorption, some manganese remains free, but most is bound to transferrin, albumin, and plasma alpha-2-macroglobulin.
Calcium is absorbed by active transport (transcellularly) and by passive diffusion (paracellularly) across the intestinal mucosa. Active transport of calcium is dependent on the action of calcitriol and the intestinal vitamin D receptor (VDR).
Following single oral administration of sodium selenate concentrations ranging from 1 mg Se/kg to 4 mg Se/kg in lambs, the peak plasma concentrations ranged from 0.79 mg Se/L to 2.54 mg Se/L. The time to reach peak plasma concentrations ranged from 7 to 12 hours.

5.3 Preclinical safety data
None stated.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Talc Powder, Magnesium Stearate, Methyl Paraben, Propyl Paraben

6.2 Incompatibilities
None stated except as in 'Interactions with other medicaments.

6.3 Shelf life
36 months

6.4 Special precautions for storage
Store below 30°C.
Keep away from light

6.5 Nature and contents of container

10 capsules blistered in aluminlum foil and PVC.

6.6 Special precautions for disposal and other handling
None

7. APPLICANT/HOLDER OF CERTIFICATE OF PRODUCT REGISTRATION

Sterling Biopharma Ltd.

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8. DRUG PRODUCT MANUFACTURER

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9. NAFDAC REGISTRATION NUMBER(S)

Not available