SUMMARY OF PRODUCT CHARACTERISTICS

(SmPC)

Of

DE-SHALOM MULTIVITAMIN SYRUP

1. NAME OF THE MEDICINAL PRODUCT

De-Shalom Multivitamin Syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains:

Vitamin C	40000mcg
Vitamin A	1000 I.U
Vitamin D	200 I.U
Vitamin B1 (Thiamine)	1500mcg
Vitamin B12 (Cyanocobalamine)	2500ng
Vitamin B2	1500mcg
Nicotinamide	10000mcg

3. PHARMACEUTICAL FORM

Oral Liquid Syrup.

Yellowish - brown syrupy liquid

4. CLINICAL PARTICULARS

4.1 Therapeutics indications

De-Shalom multivitamin syrup is used as a supplement for the prevention of vitamin deficiency in conditions such as galactosaemia, disaccharide intolerance, phenylketonuria and other disorders of carbohydrate or amino acid metabolism, as well as in patients who are on restricted, specialized, or synthetic diets.

4.2 Posology and method of administration

For Oral use.

Dosage

1 – 5 years: One 5ml teaspoonful daily.

*6 - 12 years: T*wo 5ml teaspoonful daily.

4.3 Contraindications

Contraindicated in patients known to be hypersensitive to any of multivitamin syrup components and in patients with hypervitaminosis.

4.4 Special warnings and precautions for use

The recommended dose should not be exceeded without medical advice. No other vitamin supplement containing Vitamins A and D should be taken with the De-Shalom multivitamin syrup except under medical supervision.

Warning: Do not exceed the stated dose

4.5 Interaction with other medicinal products and other forms of interaction

Absorption of some vitamins in this preparation may be reduced in conditions of fat malabsorption or with the concurrent use of neomycin, colestyramine, liquid paraffin, aminoglycosides, aminosalicylic acid, anticonvulsants, biguanides, chloramphenicol, cimetidine, colchicine, potassium salts and methyl dopa.

Serum B12 concentrations may be decreased by concurrent administration of oral contraceptives.

4.6 Fertility, pregnancy and lactation

Pregnancy

Caution should be used in pregnancy as excessive doses of Vitamin A may be teratogenic, especially when taken in the first trimester.

Breast-feeding

Large doses of Vitamin D in lactating mothers may cause hypercalcaemia in infants.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Generally multivitamin are well tolerated by the body. Sometimes, reactions could occur, but they disappear rapidly after continuous and regular use.

Ascorbic Acid (C), Nicotinamide, Pyridoxine (B6), Riboflavin (B2) & Thiamine (B1);

these water-soluble vitamins are generally nontoxic compounds with a wide margin of safety, the excess amounts being rapidly excreted in the urine.

4.9 Overdose

De-Shalom multivitamin is usually well tolerated. Large doses may cause diarrhoea and other gastro-intestinal disturbance and the formation of renal calcium oxalate calculi.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group Combinations of vitamins. The product is a multivitamin supplemental product.

Mechanism of action

De-Shalom multivitamin syrup is a Vitamins Syrup. The pharmacokinetics of the active substances would not be different from those naturally derived by food orally. In addition to serving as cofactors in biochemical reactions, the vitamin B complex is vital for normal body growth and development, healthy skin, the proper function of nerves and the heart, and red blood cell formation.

Vitamin A

Vitamin A plays an important role in the visual process. It is isomerised to the 11-cis isomer and subsequently bound to the opsin to form the photoreceptor for vision under subdued light. One of the earliest symptoms of deficiency is night blindness which may develop into the more serious condition xerophthalmia. Vitamin A also participates in the formation and maintenance of the integrity of epithelial tissues and mucous membranes.

Deficiency may cause skin changes resulting in a dry rough skin with lowered resistance to minor skin infections. Deficiency of Vitamin A, usually accompanied by protein-energy malnutrition, is linked with a frequency of infection and with defective immunological defence mechanisms.

Vitamin D

Vitamin D is required for the absorption of calcium and phosphate from the gastrointestinal tract and for their transport. Its involvement in the control of calcium metabolism and hence the normal calcification of bones is well documented. Deficiency of Vitamin D in children may result in the development of rickets.

Vitamin B1 (Thiamine)

Thiamine (as the coenzyme, thiamine pyrophosphate) is associated with carbohydrate metabolism. Thiamine pyrophosphate also acts as a co-enzyme in the direct oxidative pathway of glucose metabolism. In thiamine deficiency, pyruvic and lactic acids accumulate in the tissues. The pyruvate ion is involved in the biosynthesis of acetylcholine via its conversion to acetyl co-enzyme A through a thiamine-dependent process. In thiamine deficiency, therefore, there are effects on the central nervous system due either to the effect on acetylcholine synthesis or to the lactate and pyruvate accumulation. Deficiency of thiamine results in fatigue, anorexia, gastro-intestinal disturbances, tachycardia, irritability and neurological symptoms. Gross deficiency of thiamine (and other Vitamin B group factors) leads to the condition beri-beri.

Vitamin B2 (Riboflavine)

Riboflavine is phosphorylated to flavine mononucleotide and flavine adenine dinucleotide which act as co-enzymes in the respiratory chain and in oxidative phosphorylation. Riboflavine deficiency presents with ocular symptoms, as well as lesions on the lips and at angles of the mouth.

Vitamin B12 (Cyanocobalamin)

Vitamin B12 is present in the body mainly as methylcobalamin and as adenosylcobalamin and hydroxocobalamin. These act as co-enzymes in the trans methylation of homocysteine to methionine; in the isomerisation of methylmalonyl co-enzyme to succinyl co-enzyme and with folate in several metabolic pathways respectively. Deficiency of Vitamin B12 interferes with haemopoiesis and produces megaloblastic anaemia.

Nicotinamide

The biochemical functions of nicotinamide as NAD and NADP (nicotinamide adenine dinucleotide phosphate) include the degradation and synthesis of fatty acids, carbohydrates and amino acids as well as hydrogen transfer. Deficiency produces pellagra and mental neurological changes.

5.2 Pharmacokinetic properties

Vitamin A palmitate

Vitamin A palmitate is hydrolysed in the intestinal lumen to retinol which is then absorbed. Retinol circulates in the blood bound to retinol binding protein which protects it from glomerular filtration. The complex circulates to target tissues where the vitamin is released, permeates the cell and binds intracellularly to cellular retinol binding protein. Of the absorbed retinol 20 - 50 % is either conjugated or oxidised to various products and excreted over a matter of days in the urine and faeces, while the remainder is stored. This stored retinol is gradually metabolised by the liver and peripheral tissues.

Vitamin D

Vitamin D circulates in the blood associated with vitamin D binding protein. It is stored in fat deposits. Calciferol is hydroxylated in the liver and gut to 25-hydroxy colecalciferol which is then further metabolised in the kidney to the active form 1,25-dihydroxycolecalciferol and other hydroxylated metabolites. Calciferol and its metabolites are excreted largely in bile with eventual elimination in the faeces, with only small amounts of some of the metabolites appearing in the urine.

Thiamine hydrochloride (Vitamin B1)

Thiamine has a plasma half life of 24 hours and is not stored to any great extent in the body. Excess ingested thiamine is excreted in the urine as either the free vitamin or as the metabolite, pyrimidine.

Riboflavin (Vitamin B2)

Following absorption riboflavin is converted into the co-enzymes: flavin ononucleotide (FMN) and flavin adenine dinucleotide (FAD).Riboflavin is not stored in body tissues to any great extent and amounts in excess of the body's requirements are excreted in the urine largely unchanged.

Nicotinamide

Nicotinamide is readily taken up into tissues and utilised for the synthesis of the co-

enzyme forms nicotinamide adenine dinucleotide (NAD) and nicotinamide adenine dinucleotide phosphate (NADP).

Nicotinamide is degraded in the liver and other organs to a number of products that are excreted in the urine, the major metabolites being n-methyl-2-pyridone-5-carboxamide and n-methylnicotinamide

Vitamin C

Ascorbic acid is absorbed in the proximal small intestine in a dose-dependent manner. The bioavailability drops with increasing dosage to 60 - 75% after 1 g, to approx. 40% after 3 g and approx. 16% after 12 g. The portion which is not absorbed is broken down by the large intestinal flora into CO_2 and organic acids.

The maximal metabolic turnover of 40 to 50 mg/day in healthy adults is reached at plasma concentrations of 0.8 to 1.0 mg/dl. The total daily turnover is about 1 mg/kg BW. Brief plasma concentrations of up to 4.2 mg/dl are achieved about three hours after applying extremely high oral doses.

Under these circumstances ascorbic acid is eliminated in the urine by up to 80%. The half-life constitutes 2.9 hours on average. Renal elimination ensues via glomerular filtration and subsequent reabsorption in the proximal tubule.

The total body content of ascorbic acid is at least 1.5 g following a high dose of about 180 mg daily. Ascorbic acid is concentrated in the pituitary gland, adrenal glands, lenses of the eye and white blood cells.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on studies of single and repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction as reported in scientific literatures.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Sucrose
- Propylene glycol
- Glycerine
- Methyl Paraben
- Propyl paraben
- Dextrose
- EDTA
- Banana flavour
- Pineapple flavour
- C.M.C
- Ethanol

6.2 Incompatibilities

None known

6.3 Shelf life

18 months.

6.4 Special precautions for storage

Store below 30 °C. Keep away from sunlight.

Keep out of reach of children.

6.5 Nature and contents of container

100ml amber bottle in a cardboard carton

6.6 Special precautions for disposal and other handling

No special requirements apart from NAFDAC guidelines

7 MARKETING AUTHORISATION HOLDER

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