1. NAME OF THE MEDICINAL PRODUCT

De-Shalom Multivitamin Syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains:

Vitamin C	40000mcg/5ml
Vitamin A	1000 I.U/5ml
Vitamin D	200 I.U/ml
Vitamin B1 (Thiamine)	1500mcg/ml
Vitamin B12 (Cyanocobalamine)	2500ng
Vitamin B2	1500mcg/5ml
Nicotinamide	10000mcg/5ml

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.

De-Shalom multivitamin is essential for the maintenance of healthy growth. Deficiency in the intake of multivitamin is characterized by capillary fragility and bleeding (especially from the gum), anaemia, cartilage/bone lesion and slow healing of wounds.

Method of administration

Children: One 5ml teaspoonful daily.

*Adults and children and above 6 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 and multiminerals 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 multiitamin is usually well tolerated. Large doses are reported to cause diarrhoea and other gastro-intestinal disturbance and are associated with 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.

5.2 Pharmacokinetic properties

Multivitamin 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 CO2 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.

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.

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

No Incompatibility.

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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