LSP Multivitamin Syrup for Infant

1. Name of the medicinal product

LSP Multivitamin Syrup for Infant

2. Qualitative and quantitative composition

LSP Multivitamin Syrup for Infant each mL contains:

			%RDA
Vitamin A Palmitate (1,000,000 IU/g)			
equivalent to Vitamin A	1500	IU	180%
Cholecalciferol (Vitamin D3) (1,000,000 IU/g)			
equivalent to Vitamin D3	400	IU	100%
Thiamine hydrochloride (Vitamin B1)	0.50	mg	166.67%
Riboflavin (Vitamin B2)	0.50	mg	125%
Pyridoxine hydrochloride (Vitamin B6)	0.50	mg	166.67%
Cyanocobalamin (Vitamin B12)	0.60	mcg	120%
Ascorbic acid (Vitamin C)	50.00	mg	100%
Nicotinamide	5.00	mg	125%

3. Pharmaceutical form

Oral Syrup.

Orange syrup, orange flavor.

4. Clinical particulars

4.1 Therapeutic indications

LSP Multivitamin Syrup for Infant is indicated for the prevention of vitamin deficiencies during the 6 to 11 months of infancy.

4.2 Posology and method of administration

Adults and children over 11 months:

Not appropriate.

Infant aged 6 to 11 months:

Oral. One 0.5 ml dose taken twice daily.

Maximum daily dose: 1.0 ml.

Elderly:

Not appropriate

Hepatic/renal dysfunction:

Normal dosage is appropriate.

4.3 Contraindications

LSP Multivitamin Syrup for Infant is contraindicated in individuals with known hypersensitivity to the product or any of its components.

4.4 Special warnings and precautions for use

When prescribing LSP Multivitamin Syrup for Infant, as with all multi-vitamin preparations, allowance should be made for vitamins obtained from other sources.

While infant is taking LSP Multivitamin Syrup for Infant no other vitamin supplement containing vitamins A and D should be taken unless under medical supervision.

This multivitamin supplement should not be given to babies who are receiving more than 500 ml of formula milk per day to avoid exceeding the safe upper limit of Vitamin A.

Excessive dosage of vitamin A and D may lead to hypervitaminoses. Due allowance should always be made for intake of these vitamins from other sources.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

None.

4.6 Pregnancy and lactation

Not indicated.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Vitamin A palmitate

Adverse effects are extremely rare at daily doses of less than 9 mg (16363.6 IU).

Cholecalciferol (Vitamin D3)

The only known adverse effects of vitamin D occur when excessive doses are taken. Adverse effects are not anticipated at the quantity present in LSP Multivitamin Syrup for Infant.

Ascorbic Acid (Vitamin C), Nicotinamide (Vitamin B3), Pyridoxine hydrochloride (Vitamin B6), Riboflavin (Vitamin B2) & Thiamine hydrochloride (Vitamin B1)

These water-soluble vitamins are generally non-toxic compounds with a wide margin of safety, the excess amounts being rapidly excreted in the urine. Adverse effects are not anticipated at the quantities present in LSP Multivitamin Syrup for Infant.

4.9 Overdose

Symptoms and signs

LSP Multivitamin Syrup for Infant contains levels of vitamins which present little risk in overdose.

Vitamin A palmitate

Acute administration of high doses of vitamin A can cause headache, nausea, vomiting and irritability. In infants acute toxicity can lead to transient hydrocephalus. All these effects disappear within 24 hours of taking retinol.

Cholecalciferol (Vitamin D3)

Excessive doses of vitamin D, 60,000 units per day, can result in hypercalcaemia and hypercalciuria. Adverse effects of hypercalcaemia may include muscle weakness, apathy, headache, anorexia, nausea and vomiting, hypertension and cardiac arrhythmias.

Thiamine hydrochloride (Vitamin B1)

When taken orally, thiamine is non-toxic. If large doses are ingested they are not stored by the body but excreted unchanged by the kidneys.

Riboflavin (Vitamin B2)

Riboflavin has been found to be practically non-toxic.

Pyridoxine hydrochloride (Vitamin B6)

Acute doses less than 500 mg per day appear to be safe. Excessive doses may lower serum folate concentrations. Sensory neuropathy has been described with chronic dosing of 200 mg daily.

Nicotinamide (Vitamin B3)

A single large overdose of nicotinamide is unlikely to have serious ill effects, though transient abnormalities of liver function might occur.

Ascorbic acid (Vitamin C)

Ascorbic acid is not stored to a great extent by the body, any excess amounts are eliminated in the urine. Ascorbic acid is thought to become toxic at chronic doses in excess of 6 g.

Treatment

Treatment should be supportive and symptomatic.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Vitamin A palmitate

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.

Cholecalciferol (Vitamin D3)

Vitamin D is a regulator of both calcium and phosphate homeostasis.

Thiamine hydrochloride (Vitamin B1)

Vitamin B is essential for proper carbohydrate metabolism and plays an essential role in the decarboxylation of alpha keto acids.

Riboflavin (Vitamin B2)

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.

Pyridoxine hydrochloride (Vitamin B6)

Vitamin B is a constituent of the co-enzymes, pyridoxal pyrophosphate and pyridoxamine phosphate, both of which play an important role in protein metabolism.

Nicotinamide (Vitamin B3)

Nicotinamide is an essential component of co-enzymes responsible for proper tissue respiration.

Ascorbic acid (Vitamin C)

Ascorbic acid is a water-soluble vitamin and a powerful antioxidant.

It is a cofactor in numerous biological processes, such as the metabolism of folic acid, amino acid oxidation and the absorption and transport of iron.

It is also required for the formation, maintenance and repair of intercellular cement material. Ascorbic acid is important in the defense against infection, the normal functioning of T-lymphocytes and for the effective phagocytic activity of leucocytes. It also protects cells against oxidation damage to essential molecules.

5.2 Pharmacokinetic properties

Absorption

Vitamins A, B1, B2, B6, C, D and nicotinamide are well absorbed from the gastro-intestinal tract.

Distribution

The vitamins present in LSP Multivitamin Syrup for Infant are widely distributed to all tissues in the body.

Metabolism and elimination

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 feces, while the remainder is stored. This stored retinol is gradually metabolised by the liver and peripheral tissues.

Cholecalciferol (Vitamin D3)

Vitamin D circulates in the blood associated with vitamin D binding protein. It is stored in fat deposits. Cholecalciferol, by itself cholecalciferol is inactive. It is converted to its active form by two hydroxylations; the first in the liver, by CYP2R1 or CYP27A1, to form 25-hydroxycholecalciferol (calcifediol, 25-OH vitamin D_3). The second hydroxylation occurs mainly in the kidney through the action of CYP27B1 to convert 25-OH vitamin D_3 into 1,25-dihydroxycholecalciferol (calcitriol, 1,25-$(OH)_2$vitamin D_3). All these metabolites are bound in blood to the vitamin D-binding protein. The action of calcitriol is mediated by the vitamin D receptor, a nuclear receptor which regulates the synthesis of hundreds of proteins and is present in virtually every cell in the body. Cholecalciferol 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 mononucleotide (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.

Pyridoxine hydrochloride (Vitamin B6)

The half-life of pyridoxine ranges from 15 - 20 days. Once absorbed vitamin B6 is converted to its active co-enzyme form pyridoxal 5-phosphate. Muscle is the major storage site for pyridoxal 5-phosphate. It is degraded in the liver to 4-pyridoxic acid which is eliminated by the kidneys.

Nicotinamide (Vitamin B3)

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.

Ascorbic acid (Vitamin C)

Ascorbic acid reaches a maximum plasma concentration 4 hours following oral administration after which there is rapid urinary excretion. Following oral administration 60% of the dose is excreted in 24 hours either as ascorbic acid or its metabolite dihydroascorbic acid.

Pharmacokinetics in Renal Impairment

There have been no specific studies of LSP Multivitamin Syrup for Infant in renal impairment.

Pharmacokinetics in the Elderly

Not appropriate.

5.3 Preclinical safety data

Mutagenicity

There is insufficient information to determine the mutagenic potential of the active ingredients. However very large doses of vitamin C are claimed to be mutagenic.

Carcinogenicity

There is insufficient information to determine the carcinogenic potential of the active ingredients.

Teratogenicity

High doses of vitamin D are known to be teratogenic in experimental animals, but direct evidence for this is lacking in humans.

The teratogenicity of vitamin A in animals is well known, both high and low levels of the vitamin result in defects. But the significance of this for humans is in dispute. Synthetic versions of vitamin A (Isotretinoin and Etretinate) have been shown to be powerful teratogens. There is insufficient information to determine the teratogenic potential of the other active ingredients.

Fertility

Not appropriate.

6. Pharmaceutical particulars

6.1 List of excipients

Polyoxyl 40 Hydrogenated Castor Oil

Sucralose

Xanthan gum

Orange flavor

Polyethylene glycol 400

Sunset yellow CI. No.15985

Methylparaben

Propylparaben

Purified water

Sorbitol solution

6.2 Incompatibilities

None known.

6.3 Shelf life

24 months after manufacture.

Once opened use within 4 weeks.

6.4 Special precautions for storage

Do not store above 25°C. Protect from light. Keep bottle in the outer carton.

Refrigerate (at 2-8°C) after opening. Do not freeze. Should be used within four weeks (28 days).

6.5 Nature and contents of container

LSP Multivitamin Syrup for Infant is presented in amber plastic (PET) bottle (15 mL) with pilter proof aluminium cap (22 mm) and packed with the plastic syringe (1 mL) without needle in mono carton along with the product information.

6.6 Special precautions for disposal and other handling

Not applicable.

7. Marketing authorisation holder and Manufacturer

Lerd Singh Pharmaceutical Factory Limited Partnership

922, Sukhumvit 50, Sukhumvit Road, Phra Khanong, Klong Toey, Bangkok, 10260 Thailand

8. Registration Number

Not applicable.

9. Date of first authorisation/renewal of the authorisation

Not applicable.

10. Date of revision of the text

Oct 5th, 2021