



National Agency for Food & Drug Administration & Control (NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

SUMMARY OF PRODUCT CHARACTERISTICS



UGOLAB PRODUCTIONS (NIG.) LTD.

MANUFACTURERS OF PHARMACEUTICAL PRODUCTS AND GENERAL MERCHANTS

Head office: 31A Burma Road, Sabon Gari, Kano.

Factory: 157/159, Club Road, Bompai Ind. Layout, Kano.

Tel: +234 (80) 23094219

Website: www.ugolab.com

Email: ugolabpharm@yahoo.com

SUMMARY OF PRODUCT CHARACTERISTICS

LABVITE

1. NAME OF THE MEDICINAL PRODUCT

Labvite syrup, Labvite Drops

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.6ml Labvite Drops contains,

VITAMIN 400IU

VITAMIN B1 1mg

VITAMIN B2 0.4mg

NICOTINAMIDE 5mg

VITAMIN C 25mg

VITAMIN D 400IU

Each 5ml Labvite multivitamin syrup contains,

VITAMIN A 1,000IU

VITAMIN B1 1500MCG

VITAMIN B2 1500MCG

NICOTINAMIDE 10.0MG

VITAMIN C 50.0MG

VITAMIN D 200IU



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Excipients:

Each ml contains 0.7mg Methylparaben

{For a full list of excipients, see section 6.1}

3. PHARMACEUTICAL FORM

Syrup

An Orange colored syrup.

4. Clinical particulars

4.1 Therapeutic indications

Labvite 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

Posology

Shake well before use.

Labvite multivitamin syrup is for adults, children and the elderly: 5 ml daily.



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Method of administration

For oral use

4.3 Contraindications

Contraindicated in patients known to be hypersensitive to any of Labvite 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 Labvite multivitamin syrup except under medical supervision.

Warning: do not exceed the stated dose.

Methyl paraben

This medicinal product contains methyl paraben. May cause allergic reactions (possibly delayed).

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,



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colestyramine, liquid paraffin, aminoglycosides, aminosalicic 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 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.

Labvite multivitamin syrup has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

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



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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

Seek emergency medical attention. Most reported, symptoms of Vitamins & amino acid overdose include nausea and vomiting.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Pharmacotherapeutic group Combinations of vitamins.

The product is a multivitamin supplemental product.

Mechanism of action

Labvite multivitamin syrup is a Vitamins Syrup. The pharmacokinetics of the active substances would not be different from those naturally derived by food orally. Vitamin stimulates 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.



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5.2 Pharmacokinetic properties

The pharmacokinetics of the active substances would not differ from that of the same substance when derived naturally from oral foodstuffs.

5.3 Preclinical safety data

Non-Stated

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

NA SACCHARINE

PROPYL PARABEN

METHYL PARABEN

NATROSOL

PROPYLENE GLYCOL

GLYCERINE

SORBITOL

STRAWBERRY FLAVOUR

6.2 Incompatibilities

Non-Known



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6.3 Shelf life

24 Months

6.4 Special precautions for storage

Store below 30°C in a dry place. Protect from light.

6.5 Nature and contents of container <and special equipment for use administration or implantation>

Bottle:	Amber PET, Plain PET
Closures:	28mm ROPP, tamper evident, child resistant.
Pack Sizes:	100m x 60. 15ml x 48 2L x6

6.6 Special precautions for disposal <and other handling>

As for all medicines – no special requirements.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required (these should be disposed of in line with local requirements). These measures will help to protect the environment.



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7. APPLICANT/MANUFACTURER

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