SUMMARY PRODUCT CHARACTERISTICS

1. Name of the medicinal product

MEDIBOOST SYRUP (Multivitamin syrup)

2. Quantitative composition

Each 5ml contains:

Vitamin A (as Palmitate) .....2500 I.U.
Vitamin B1 .....1.5mg
Vitamin B2 .....1.5mg
Vitamin B6 .....1.0mg
Vitamin C 25mg

For full list of excipients refer to section 6.1

3. Pharmaceutical form Syrup

A yellow coloured syrupy liquid with a pleasant odour and a sweet taste.

4. Clinical particulars

4.1 Therapeutic indications

Multivitamin syrup is indicated for the prevention of vitamin deficiencies and for the maintenance of normal growth and health during the early years of infancy and childhood, multivitamin supplement.

4.2 Posology and method of administration

Posology

Children upto 2yrs. old: ½ teaspoonful daily
Children over 2yrs. old: 1 teaspoonful daily
Adults: 1 to 2 teaspoonsful daily.

Method of administration

For oral administration.

4.3 Contraindications

Multivitamin syrup is contraindicated in individuals with known hypersensitivity to the product or any of its component including peanut oil.

Multivitamin syrup contains Arachis oil (peanut oil) and should not be taken by patients known to be allergic to peanut. As there is a possible relationship between allergy to peanut and allergy to Soya, patients with Soya allergy should also avoid Multivitamin syrup.

4.4 Special warnings and precautions for use

When Prescribing multi-vitamin preparation, allowance should be made for vitamins obtained from other source.

While children are taking Multivitamin syrup no other vitamin supplement containing vitamin A and D should be taken unless under medical supervision.
This Multivitamin syrup should not given to babies who are receiving more than 500mls of formula milk per day to avoid exceeding safe upper limit of Vitamin A.
Excessive dosage of vitamin A and D may lead to hypervitaminoses. Due allowance shloud always be made for intake of these vitamins fom other sources.
Patients with rare heredity problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicibe.

4.5 Interaction with other medicinal products and other forms of interaction:

No clinically significant interactions are expected at the recommended doses.
However:

- **Vitamin A (retinol derivatives)**: Concurrent use with other vitamin A-containing products may increase the risk of hypervitaminosis A.
- **Vitamin B6 (pyridoxine)**: May reduce the efficacy of levodopa when administered without a dopa decarboxylase inhibitor.
- **Nicotinamide**: High doses may potentiate the effects of antihypertensive agents.
- **Vitamin C (ascorbic acid)**: May enhance iron absorption and can affect the bioavailability of certain medicines (e.g., deferoxamine).

Patients should be advised to inform their healthcare provider if they are taking other vitamin supplements or medications.

4.6 Fertility, pregnancy and lactation:

This product is not specifically indicated for use during pregnancy or lactation.

- **Pregnancy**:
  Vitamin A intake in excess of recommended daily allowances may be teratogenic. The amount present in this product is within the recommended daily intake; however, caution should be exercised to avoid concurrent use with other vitamin A-containing products.
- **Lactation**:
  The vitamins in this formulation are excreted into breast milk in small amounts and are generally considered safe at nutritional doses.
- **Fertility**:
  No adverse effects on fertility are known at recommended doses.

Use during pregnancy and lactation should be based on medical advice.

4.7 Effects on ability to drive and use machines:

This product has no or negligible influence on the ability to drive and use machines

4.8 Undesirable effects

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

Ascorbic acid (C), Nicotinamide, Pyridoxine(B6), Riboflavin(B2)&Thiamine(B1): These water soluble vitamins are generally non toxic compounds with wide margin of safety , the excess amount being rapidly excreted in the urine. Advese effects are not anticipated at the quantities present in Multivitamin syrup.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to National Regulatory Agents

4.9 Overdose

a) Symptoms and sign: Multivitamin syrup contains levels of vitamin which present little risk in overdose.

Vitamin A: acute administration of high doses of vitamin A can cause headache, nausea,vomiting and irritability.

Vitamin B1: when taken orally, thiamine is non toxic . If large doses are ingested they are not stored by the but excreted unchanged by the kidneys.

Vitamin B2: Riboflavin has been found to practically be non toxic.

Vitamin B6: Acute doses less than 500mg per day appear to be safe. Excessive doses may lower serum folate concentration. Sensory neuropathy has been described with chronic dosing of 200mg daily

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

Vitamin C: Ascorbic acid is not stored to a greater extent by the body , any exess amounts are eliminated in the urine . Ascorbic acid is thought to become toxic at chronic dose in excess of 6g.

Treatment: Treatment should be supportive and symptomatic.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Vitamin A : It plays an essential role in the function of the retina, the growth and function of epithelial tissue, bone growth, reproduction and embryonic development.

Vitamin B1: It is essential for proper carbohydrate metabolism and plays an essential role in the which plays in decarboxylation of alpha keto acid.

Vitamin B1: Riboflavin is essential role for utilisation of energy from food . It is component of co-enzymes which plays an essential role in oxidative/reductive metabolic reaction.

Riboflavin is also necessary for the functioning of pyridoxine and nicotinic acid.

Vitamin B6: Vitamin B6 is constituent of co-emzymes, pyridoxal pyrophosphate and pyridoxamine phosphate, both of which play important role in protein metabolism.

Nicotinamide: It is essential component to co-enzymes responsible for proper tissue respiration .

Vitamin C : Ascorbic acid is water soluble vitamin and powerful antidoxidant.

5.2 Pharmacokinetic properties.

Absorption: Vitamin A,B1,B2,B6 ,C,D and Nicotinamide are well absorbed from the gasro- intestinal tract.
Distribution: The vitamin present in Multivitamin syrup are widely distributed to all tissues in the body.
Metabolism and elimination
Vitamin A: It is hydrolysed in the intestinl lumen to retinol which is then absorbed. Retinol circulates in the blood bound to retinol binding protein which protects it from glomerular filtration.
Vitamin B1: Thiamine has plasma half life of 24 hours and is not stored to any in great extent in the body. Excess ingested thiamine is excreted in the urine as either the free vitamin or as the metabolite, pyrimidine.
Vitamin B2: Following absorption Riboflavin is converte into co-enzyme: 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.
Vitamin B6: The half life of pyridoxine ranges from 15-20 days. Once absorbed vitamin B6 converted to its active co-enzyme from pyridoxal 5-phosphate. Muscle is major storage site for pyridoxal 5-phosphate.
Nicotinamide: It is readily taken up into tissues and utilised for the synthesis of co-enzyme forms nicotinamide adenine dinucleotide (NAD) and adenine adenine dinucleotide phosphate (NADP).
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 dose is excreted in 24 hours either as ascorbic acid or its metabolite dihydroascorbic acid.

5.3 Preclinical safety data

The active ingredients in this product (Vitamin A, B-complex vitamins, Vitamin C, and nicotinamide) are well-known substances with established safety profiles and have been widely used in clinical practice for many years.

Preclinical data for the individual components indicate the following:

- **Vitamin A (as palmitate)**:
  High doses in animal studies have demonstrated toxicity, including teratogenicity, hepatotoxicity, and skeletal abnormalities. These effects are associated with doses significantly higher than those recommended for human use.
- **Vitamin B1 (thiamine), Vitamin B2 (riboflavin), and Vitamin B6 (pyridoxine)**:
  These vitamins have low toxicity profiles. Adverse effects in animal studies are rare and generally occur only at very high doses. Prolonged

administration of excessive doses of pyridoxine has been associated with sensory neuropathy.

- **Vitamin C (ascorbic acid)**:
  Demonstrates very low toxicity in animal studies. High doses may be associated with gastrointestinal disturbances and, in rare cases, oxalate stone formation.
- **Nicotinamide**:
  Generally well tolerated in animal studies. Very high doses have been associated with hepatotoxicity.

No additional preclinical toxicity studies have been conducted on this specific combination product. However, based on the long history of safe use of the individual components at nutritional doses, no special hazard for humans is expected when used as recommended

6. Pharmaceutical particulars

6.1 List of excipients

Sorbitol
Sodium methyl paraben
Sodium propyl paraben
Tween 80
Mixed fruit essence
Sodium Hydroxide
Tartrazine Colour
CMC
Sodium Saccharin
Sodium benzoate
Sodium Metabisulphate
Sodium EDTA
Potassium sorbate
De-ionised water to make up volume

6.2 Incompatibilities
Not Applicable

6.3 Shelf life
2 years

6.4 Special precautions for storage
Store below 30°C. Protect from light and moisture.

6.5 Nature and contents of container
60ml and 100ml.

6.6 Special precautions for disposal and other handling:

Store in dry place below 30°C. Protect from light. Maintain this medication in well closed container.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURER

Marketing Authorisation Holder:

Medina Chemical Remedies Gateway Place,

Milimani Road, P.O BOX 47346-00100,

Nairobi ,Kenya

Marketing Authorization Number:

CTD12972

8. Date of First <Registration> / Renewal of The <Registration>

1st May,2026

Date of Revision of the Text:
1st May,2026