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

Registration & Regulatory Affairs (R & R) Directorate

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

BIOMULT ORAL LIQUID

1. NAME OF THE MEDICINAL PRODUCT

Biomult Oral Liquid

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Vitamin A (as palmitate)	1500 IU
Vitamin D3	100 IU
Vitamin E (acetate)	3mg
Vitamin B1(as Thiamine Hydrochloride)	1.5 mg
Vitamin B2 (as Riboflavin-5-Phosphate Sodium)	1.5 mg
Vitamin B6(as pyridoxine Hydrochloride)	1mg
Vitamin B12(Cyanocobalamin)	1.5mcg
D-Panthenol	2.5mg
Niacinamide	5mg
Vitamin C	30 mg
L-Lysine Hydrochloride	40mg
Ferrous Gluconate	42.85mg
Zinc Gluconate	34.85mg
Magnesium Gluconate	185.41mg

3. PHARMACEUTICAL FORM

Syrup

4. Clinical particulars

4.1 Therapeutic indications

Dietary supplement for children between the ages of 2 and 12years. Treatment/prevention of low levels of vitamins.

4.2 Posology and method of administration

Infant: 2.5ml twice a day.
Children (1-4 years): 5ml twice a day.
Children (4-12 years): 5ml thrice a day.

4.3 Contraindications

Biomult Oral Liquid 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 Biomult Oral Liquid, as with all multi-vitamin preparations, allowance should be made for vitamins obtained from other sources.

While children are taking Biomult Oral Liquid 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 500mls of formula milk per day to avoid exceeding the safe upper limit of Vitamin A

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

The only known adverse effects of vitamin D occur when excessive doses are taken. Adverse effects are not anticipated at the quantity present in Biomult Oral Liquid.

Nicotinamide, Pyridoxine (B_6), Riboflavin (B_2) & Thiamine (B_1)

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 arenot anticipated at the quantities present in Biomult Oral Liquid

4.9 Overdose

Biomult Oral Liquid contains levels of vitamins which present little risk in overdose.

Vitamin A

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.

Thiamine hydrochloride (Vitamin B_1)

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 B_2)

Riboflavin has been found to be practically non-toxic.

Pyridoxine hydrochloride (Vitamin B_6)

Acute doses less than 500mg 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

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

Treatment

Treatment should be supportive and symptomatic

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Vitamin A

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.

Thiamine hydrochloride (Vitamin B_1)

Vitamin B_1 is essential for proper carbohydrate metabolism and plays an essential role in the decarboxylation of alpha keto acids.

Riboflavin (Vitamin B_2)

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 B_6)

Vitamin B_6 is a constituent of the co-enzymes, pyridoxal pyrophosphate and pyridoxamine phosphate, both of which play an important role in protein metabolism.

Nicotinamide

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

5.2 Pharmacokinetic properties

Absorption

Vitamins A, B1, B2, B6, D3 and nicotinamide are well absorbed from the gastro-intestinal tract.

Distribution

The vitamins present in Biomult Oral Liquid are widely distributed to all tissues in the body.

Metabolism and elimination

Vitamin A

Vitamin A 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.

Thiamine hydrochloride (Vitamin B_1)

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 B_2)

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 B_6)

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

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.

Pharmacokinetics in Renal Impairment

There have been no specific studies of Biomult Oral Liquid 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 Active and Excipients

Vitamin A (as palmitate)	1500 IU
Vitamin D3	100 IU
Vitamin E (acetate)	3mg
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Vitamin B2 (as Riboflavin-5-Phosphate Sodium)	1.5 mg
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L-Lysine Hydrochloride	40mg
Ferrous Gluconate	42.85mg
Zinc Gluconate	34.85mg
Magnesium Gluconate	185.41mg

6.2 Incompatibilities

None known

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store below 30°C in a dry place. Keep all medicines out of reach of children.

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

100ml syrup in an amber bottle placed in an outer carton with insert.

6.6 Special precautions for disposal <and other handling>

None applicable

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7. APPLICANT/MANUFACTURER

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