

# **MECURE INDUSTRIES PLC**

# SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

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# **1.** Name of the medicinal product

# **Olal Multivitamin Tablets**

#### 2. Qualitative and quantitative composition

Each sugar coated tablet contains:

Vitamin A Acetate BP	2500 IU
Vitamin D3 BP	250 IU
Vitamin B1 BP	0.6 mg
Vitamin B2 BP	1 mg
Vitamin C BP	13 mg

For the full list of excipients, see section 6.1.

#### 3. Pharmaceutical form

Tablet

Brown colored, circular, biconvex shaped sugar coated tablet

#### 4. Clinical particulars

# 4.1 Therapeutic indications

**OLAL** (Multivitamin Tablets) is given as nutritional supplement and also given along with Antibiotic therapy. It is also prescribed / given during growth, during lactation, under stress, in fevers and other catabolic conditions such ads hyperthyroidism.

# **4.2 Posology and method of administration** Posology:

1 tablet twice daily or as directed by a physician

Method of administration: Oral

#### 4.3 Contraindications

This preparation is contra indicated in those who are hypersensitive to any of the component of multivitamin Tablets.

# 4.4 Special warnings and precautions for use

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

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

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

Interactions of iron with tetracycline antibiotics (tetracycline, doxycline, minocycline) and vitamin  $B_6$  and levodopa are known. Patients on any of these medications should seek medical advice before starting this product.

# 4.6 Pregnancy and lactation

It is safe to prescribe this preparation to pregnant woman but only under the supervision of medical practitioner.

#### **4.7 Effects on ability to drive and use machines** No studies on the effects on the ability to drive and use machines have been performed.

# 4.8 Undesirable effects

Allergic reaction (difficulty breathing; closing of throat; swelling of lips, tongue, or face; or hives).

Other, less serious side effects may be more likely to occur. Nausea, constipation, black stools, and diarrhea are among the most common.

# 4.9 Overdose

Treatment of over dosage is by supportive and symptomatic therapy. In the case of acute overdosage, according to the patient's condition, supportive therapy may include gastric lavage or emesis.

# 5. Pharmacological properties

# 5.1 Pharmacodynamic properties

Olal Tablet exert a stimulant effect at physical and psychological levels through the combined action of various substances on the basic metabolic processes.

In animal experiments, it caused a reduction of lactic acid concentration in muscles during exercise. An increase in the dopamine and noradrenaline content and a reduction in the serotonin content in the brain stem could be observed.

Vitamins, minerals and trace elements correct and prevent impairment of the cell metabolism in situations with increased demands. Low supply of vitamins, minerals, and trace elements may cause disturbances, such as debility, tiredness, decrease in vitality, reduced force of resistance, and decelerated convalescence. The composition and dosages of the preparation were chosen according to the European RDA-requirements for food supplements.

Choline, inositol, linoleic acid and linolenic acid, in the form of lecithin, improve energy output and lipid metabolism.

# 5.2 Pharmacokinetic properties

Pharmacokinetic studies of Olal Tablet have not been carried out, because of the complex composition of the product and the small quantities of the active ingredients contained. Moreover, these substances are well known.

5.3 **Preclinical safety data** Not applicable

# 6. Pharmaceutical particulars

6.1 List of excipients

Starch, Lactose, Dibasic Calcium Phosphate, Gelatin, Methyl Paraben, Propyl Paraben, Magnesium Stearate, Talcum, Chloroform, Titanium Dioxide, Calcium Carbonate, Colour Chocolate Brown, Colour Brillant Blue, Carnuba Wax.

# 6.2 Incompatibilities

None known

**6.3** Shelf life 36 months

# 6.4 Special precautions for storage

Store in a cool dry place at temperature below 30 °C. Store in the original packaging.

# 6.5 Nature and contents of container

Pack size: Jar pack of 1 x 1000's.

6.6 Special precautions for disposal and other handling Not applicable.

# 7. Marketing authorization holder

Me Cure Industries Limited

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Oshodi Industrial Scheme,

Oshodi,

Lagos,

Nigeria.

# 8.0 NAFDAC Registration Number: A4-2071