MECURE INDUSTRIES PLC

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

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1. Name of the medicinal product

Zevit Syrup (Multivitamin)

2. Qualitative and quantitative composition

Each sugar coated Syrup contains:

Vitamin A Acetate BP	1000 IU
Vitamin D3 BP	200 IU
Vitamin B1 BP	1.5 mg
Vitamin B2 BP	1.5 mg
Vitamin B12 BP	0.0025 mg
Niacinamide BP	10 mg
Vitamin C	40 mg

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Liquid

Light yellow coloured syrupy liquid having pleasant odour and taste.

4. Clinical particulars

4.1 Therapeutic indications

Healthy body, growth, good appetite, convalescence. All conditions where there is need for vitamins to withstand stress and increased demands.

4.2 Posology and method of administration

Posology:

Children: 2.5ml to 5ml

Adults: 5ml to 10ml

To be taken two times daily

Method of administration: Oral

4.3 Contraindications

Zevit Syrup is contraindicated in patients with disturbances of hypervitaminosis A or D, renal insufficiency, concomitant retinoid (e.g. for acne) or vitamin D therapy, haemochromatosis, iron overload syndrome and in patients with known hypersensitivity to any of the ingredients in the product.

4.4 Special warnings and precautions for use

Patients with a family history of haemochromatosis should seek medical advice before taking Zevit Syrup.

An allowance should be made for vitamins or minerals obtained from other sources.

In states of exhaustion (e.g. caused by stress), improvement starts usually within 4 weeks of treatment. If symptoms have not shown any improvement during that time, or you are concerned, please consult your doctor.

Each Syrup contains a small amount of lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose mal- absorption should not take this medicine.

Interference with clinical laboratory tests

Biotin may interfere with laboratory tests that are based on a biotin/streptavidin interaction, leading to either falsely decreased or falsely increased test results, depending on the assay. The risk of interference is higher in children and patients with renal impairment and increases with higher doses. When interpreting results of laboratory tests, possible biotin interference has to be taken into consideration, especially if a lack of coherence with the clinical presentation is observed (e.g. thyroid test results mimicking Graves' disease in asymptomatic patients taking biotin or false negative troponin test results in patients with myocardial infarction taking biotin). Alternative tests not susceptible to biotin interference should be used, if available, in cases where interference is suspected. The laboratory personnel should be consulted when ordering laboratory tests in patients taking biotin.

4.5 Interaction with other medicinal products and other forms of interaction

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

4.6 Pregnancy and lactation

Pregnancy and lactation

Controlled studies with women using multivitamin-mineral preparations at the usual dosage during the course of the first trimester resulted in no fetal risks. There are no signs indicating a risk if this type of preparation is taken during the second and third trimesters, and the probability of injuring the fetus appears to be very low.

Large doses of vitamin A (10,000 IU per day) have been found to be teratogenic if administered during the first trimester of pregnancy. Vitamin D given during the last trimester of pregnancy may cause hypercalcaemia in infants. As with many other medicines an assessment of benefits versus risks should be made before this product is administered during this period.

Fertility

No studies on the effect on human fertility have been conducted with Zevit Syrup.

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

Adverse events have been ranked under headings of frequency using the following convention:

Very common (≥ 1/10); common (≥ 1/100, < 1/10); uncommon (≥ 1/1000, <1/100); rare (≥ 1/10000, <1/1000); very rare (<1/10000); not known – cannot be estimated from the available data.

Immune system disorders:

Not known: hypersensitivity, anaphylactic reaction

Nervous system disorders:

Common: headache

Not known: dizziness

Gastro-intestinal disorders:

Common: nausea, vomiting

Uncommon: diarrhea

Not known: abdominal pain

Skin and subcutaneous tissue disorders:

Not known: rash, pruritus

Psychiatric disorders

Not known: insomnia

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit / risk balance of the medicinal product.

4.9 Overdose

Nervousness may occur following an overdose of the product.

The toxicity of the product in large overdoses is caused by the toxicity of the liposoluble vitamins A and D. A safe dose for both vitamins is considered to be 5-10 x RDA (each capsule contains the EU %RDA for vitamins A and D).

Prolonged supply of larger amounts corresponding to 37 capsules for vitamin A and 10 capsules for vitamin D can cause symptoms of chronic toxicity such as vomiting, headache, drowsiness, and diarrhea. Acute toxic symptoms are only seen at even higher doses.

The acute toxic dose in adult humans corresponds to about 25,000 to 50,000 IU for vitamin D (contained in 125 to 250 capsules) and about 300,000 to 900,000 IU for vitamin A (contained in 112 to 337 capsules).

Symptoms: Initial symptoms include nausea, vomiting, diarrhoea, abdominal pain, haematemesis, rectal bleeding, lethargy and circulatory collapse. Hyperglycaemia and metabolic acidosis may also occur.

Treatment: To minimise or prevent further absorption of the medication, as follows:

Induce vomiting e.g. by administration of an emetic.

Gastric lavage with desferrioxamine solution (2g/l). Then desferrioxamine (5 - 10g in 50-100ml water) should be introduced into the stomach to be retained.

Severe poisoning: Shock and/or coma with high iron levels (serum iron >90µmol/l in children, >142µmol/l in adults); immediate supportive measures plus IV infusion of desferrioxamine should be instituted.

Less severe poisoning: IM desferrioxamine is recommended (1g 4-6 hourly in children; 50mg/kg up to a maximum dose of 4g in adults).

5. Pharmacological properties

5.1 Pharmacodynamic properties

Zevit Syrup exerts a stimulant effect at physical and psychological levels through the combined action of various substances on the basic metabolic processes.

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 Zevit Syrup 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

Di-Sodium EDTA
Sodium Methyl Paraben
Sodium Propyl Paraben
Sodium Metabisulphite
Sucrose
Glycerine
Xanthan Gum
Ethanol
Sunset Yellow Supra
Mixed Fruit Flavour
Pineapple Flavour
Orange Booster Flavour
Mango Flavour
Banana Flavour
Tween-80
Citric Acid (Anhydrous)
Purified Water

6.2 Incompatibilities

None known

6.3 Shelf life

24 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

Amber coloured PET bottle with P.P cap having Me Cure printed on the body in a printed carton with a printed insert.

Pack size: Pet bottle of 100ml.

6.6 Special precautions for disposal and other handling

Not applicable.

7. Marketing authorization holder

Me Cure Industries Limited

Plot 6 Block H, Debo Industries Compound,

Oshodi Industrial Scheme,

Oshodi,

Lagos,

Nigeria.

8.0 NAFDAC Registration Number: A4-4945