MECURE INDUSTRIES PLC

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

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1. Name of the medicinal product

Zevit Liqui-Tab Float Caps, Multivitamin and Mineral Capsules with Ginseng

2. Qualitative and quantitative composition

Each Liqui-tab Float Capsule Contains:

Oil Component: Vitamin A palmitate B.P 2000 IU, Vitamin E Acetate B.P 5mg

Tablet Component:

Vitamin B1 BP. (Thiamine mono nitrate B.P)	1mg
Vitamin B2 BP (Riboflavin B.P.)	1 mg
Vitamin B6 B.P. (Pyridoxine HCL)	1 mg
Vitamin D3 BP (Cholecalciferol)	200 U
Vitamin B12 B.P (Cyanocobalamin)	1 mcg
Vitamin H B.P (biotin)	3 mcg
Potassium, Sulphate B.P. equivalent to Potassium	1mg
Selenium Dioxide USP equivalent to Selenium	50 mcg
Di Calcium phosphate B.P. equivalent to Phosphorous	15 mg
Di Calcium phosphate B,P. equivalent to Calcium	1935 mg
Magnesium Sulphate Anhydrous B.P. equivalent to Mg	1 mg
Calcium Pantothenate B.P	1 mg
Ginseng B.P	990 mcg

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Liqui-Tab Float CAPSULES

Red coloured and transparent capsule containing red tablet in an oil based capsule

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:

One Capsule daily or as directed by a physician

Method of administration: Oral

4.3 Contraindications

Zevit Liqui-Tab 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

Zevit Liqui-Tablet should not be taken during pregnancy or lactation.

Patients with a family history of haemochromatosis should seek medical advice before taking Zevit Liqui-Tab.

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.

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

In case of concomitant intake of ginseng preparations and anticoagulants, the effect of oral blood thinning medication (e.g. warfarin) may potentially be reduced. Patients on blood thinning medications should seek medical advice before starting this product.

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.

Zevit Liqui-Tablet should not be taken during pregnancy or lactation.

Fertility

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

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).

The chronic toxic dose in adult humans corresponds to about 2,000 IU for vitamin D (contained in 10 capsules) and about 100,000 IU (contained in 37 capsules) for vitamin A.

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 i.v. infusion of desferrioxamine should be instituted.

Less severe poisoning: i.m. 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 Liqui-Tab exert a stimulant effect at physical and psychological levels through the combined action of various substances on the basic metabolic processes.

The standardised ginseng extract G115 raises the general level of cellular activity, which is expressed by a pronounced increase in the physical and mental capacity.

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 Zevit Liqui-Tab 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.

Pharmacokinetic studies of the standardised ginseng extract G115 are not possible, because it is a complex extract. In the ginseng root more than 200 substances have been identified to date. Pharmacokinetic studies of individual purified ginsenosides have been carried out in various animal species:

With intraperitoneal application, depending on the tested animal species and the Ginsenoside type, a half-life of between 27 minutes and 14.5 hours was measured.

5.3 Preclinical safety data

Not applicable

6. Pharmaceutical particulars

6.1 List of excipients

Iso Propyl Alcohol, Lactose, Methylene Chloride, Micro Crystelline Cellulose, Propyl Paraben, Methyl Paraben, Talcum, Magnesium Stearate, Sodium Starch Glycolate, Colloidal Silicon Dioxide, Soyabean Oil, Gelatin Powder, Tween-80, Empty-hard gelatin Capsule.

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

Blister pack of 3 x 10’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. Marketing Authorisation number: NAFDAC NO: A4-5481