SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

ZESCO VITAMIN B-COMPLEX TABLET

2. Qualitative and quantitative composition

Each Tablet contains

Vitamin B1 BP 1mg

Vitamin B2 BP 1mg

Vitamin B6 BP 1mg

Niacinamide BP 15mg

3. Pharmaceutical form

Tablet

Yellow coloured oblong tablet

4. Clinical particulars

4.1 Therapeutic indications

Oral prophylactic and therapeutic treatment of vitamin B complex deficiency. For the treatment of clinical and sub-clinical vitamin B deficiency states (manifestations of which include glossitis, stomatitis, cheilosis, the heart manifestations of beriberi, the skin manifestations of pellagra, corneal vascularisation and polyneuritis).

4.2 Posology and method of administration

Adults: 1 tablet to be taken three times a day.

Or as prescribed by the physician.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Excipients

Lactose:

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose- galactose malabsorption should not take this medicine

4.5 Interaction with other medicinal products and other forms of interaction

The pyridoxine hydrochloride may reduce the effectiveness of levodopa.

4.6 Pregnancy and lactation

The usual precautions should be observed when administering drugs during pregnancy, especially in the first trimester.

In high doses, pyridoxine may interfere with prolactin release and should only be used with caution in nursing mothers.

4.7 Effects on ability to drive and use machines

None stated

4.8 Undesirable effects

Toxic effects are unlikely since any excess vitamin B is excreted.

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 via pv@mecure.com.

4.9 Overdose

Excess vitamin B is readily excreted; therefore no serious problems are anticipated for the administration of vitamin B in this form.

5. Pharmacological properties

5.1 Pharmacodynamic properties

The vitamin B-complex comprises a group of water-soluble factors more or less closely associated in their natural occurrence. It is known that nearly every vitamin of the B-complex forms part of a co- enzyme essential for the metabolism of protein, carbohydrate or fatty acid.

Vitamin B1: A water soluble vitamin. It is a co-enzyme for carbohydrate metabolism.

Vitamin B2: A water soluble vitamin converted in the body to flavine mononucleotide and flavine adenine dinucleotide and then involved as co-enzymes in oxidative and reductive metabolic processes.

Niacinamide: A water soluble vitamin considered part of the Vitamin B group. Converted to Nicotinamide Adenine Dinucleotide and Nicotinamide Adenine Dinucleotide Phosphate in the body, both of which are co-enzymes important in electron transfer in respiratory reactions.

Vitamin B6: A water soluble vitamin. Involved in carbohydrate and fat metabolism, but also important in haemoglobin formation.

5.2 Pharmacokinetic properties

Nicotinamide is readily absorbed from the GI tract following oral administration and is widely distributed in the body tissues. Small amounts of nicotinamide are excreted unchanged in urine following therapeutic doses, however, the amount excreted unchanged is increased with larger doses.

Pyridoxine is absorbed from the GI tract and is converted to the active form pyridoxal phosphate. It is excreted in the urine as 4-pyridoxic acid.

Riboflavine is absorbed from the GI tract and in the circulation is bound to plasma proteins. Although widely distributed, little is stored in the body, and amounts in excess of requirements are excreted in the urine.

Thiamine is absorbed from the GI tract and is widely distributed to most body tissues. It is not stored to any appreciable extent in the body and amounts in excess of requirements are excreted in the urine as unchanged thiamine or metabolites.

All the actives are water soluble vitamins. Quantities in excess of the bodies requirements are excreted either unchanged or as metabolites, mainly in the urine but to a lesser extent also in the faeces.

5.3 Preclinical safety data

None stated

6. Pharmaceutical particulars

6.1 List of excipients

Talcum

Magnesium Stearate

Microcrystalline Cellulose

Sodium Starch Glycollate

Colloidal Silicon Dioxide

Gelatin

Starch

Coating:

Isopropyl Alcohol

Sucrose

Titanium dioxide

Shellac

Calcuim carbonate

Carmine red

Acacia

Carnauba wax

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. Protect from light.

6.5 Nature and contents of container

ALU – PVC pack in a printed carton

Pack size: Blister pack of 3 x 10