SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

ZESTUP TABLET

Vitamin B Complex, sugar coated tablets

2. Qualitative and quantitative composition

Each tablet contains 1mg Vitamin B1 Mono Nitrate, 1mg Vitamin B2, 1mg Vitamin B6 and 15 mg Niacinamide.

Also contains lactose.

For a full list of excipients, see section 6.1

3. Pharmaceutical form

Sugar coated tablet.

Yellow coloured oval shaped sugar coated tablet.

4. Clinical particulars

4.1 Therapeutic indications

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 (including elderly) and children over 3 years: One to two tablets three times daily.

Children under 3 years: Not recommended.

For oral administration.

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

Pyridoxine may increase the peripheral metabolism of levodopa, reducing therapeutic efficacy of the latter drug. Therefore, patients with Parkinson's disease who are receiving treatment with plain levodopa should not take vitamin B_6 in doses which greatly exceed the daily requirement. This does not apply when levodopa is combined with a peripheral decarboxylase inhibitor.

4.6 Fertility, 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 known.

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 to the appropriate authority.

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

ATC Code: A11EA

ATC Name: Vitamin B-complex, plain

Nicotinamide is a vitamin

Pyridoxine hydrochloride is a vitamin (B_6)

Riboflavine is a vitamin (B_2)

Thiamine mononitrate is a vitamin (B_1)

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.

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.

5.3 Preclinical safety data

Not applicable.

6. Pharmaceutical particulars

6.1 List of excipients

Tablet core contains:

Lactose

Di Calcium Phosphate

Starch

Gelatin

Propyl Paraben

Methyl Paraben

Talcum

Magnesium Stearate

Sugar-coat contains:

Sucrose

Gelatin

Sodium Benzoate

Starch

Talcum

Titanium Dioxide

Calcium Carbonate

Colour Tartrazine

Carnuba Wax

6.2 Incompatibilities

None known.

6.3 Shelf life

30 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 strips of 20 μm Aluminium and 250 μm PVC in a cardboard outer container. Pack sizes: 3 blisters of 10 tablets.

6.6 Special precautions for disposal and other handling

Not applicable.

7. Marketing authorization holder

Me Cure Industries PLC

Plot 6 Block H, Debo Industries Compound,

Oshodi Industrial Scheme,

Oshodi,

Lagos,

Nigeria.

8.0 NAFDAC REGISTRATION NUMBER: A4-2163