1. Name of the medicinal product

Vitamin B Compound Tablets

2. Qualitative and quantitative composition

Each tablet contains

Vitamin B1.....1mg

Vitamin B2.....1mg

Vitamin B3.....15mg

For the full list of excipients see section 6.1.

3. Pharmaceutical form

Tablet

4. Clinical particulars

4.1 Therapeutic indications

Oral prophylactic and therapeutic treatment of vitamin B complex deficiency.

4.2 Posology and method of administration

Adult: Two tablets daily to be taken after meal

Children: One tablet daily to be taken after meal or as directed by the Physician.

4.3 Contraindications

Known sensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

No special warnings.

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

Considered safe in the recommended dose.

4.7 Effects on ability to drive and use machines

None stated

4.8 Undesirable effects

None known

4.9 Overdose

Not applicable.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Vitamin B Complex.

Thiamine Hydrochloride (Vit B1): A water-soluble vitamin. It is a co-enzyme for carbohydrate metabolism.

Riboflavin Sodium Phosphate (Vit 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.

Nicotinamide: 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.

5.2 Pharmacokinetic properties

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

Maize starch

Lactose

Magnesium stearate

Purified talc

Aerosil 200

Purified Water

6.2 Incompatibilities

None known

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 30°C. Protect from light.

6.5 Nature and contents of container

350cc Grey jar and white caps

6.6 Special precautions for disposal and other handling

None stated

7. Marketing authorization holder

Distributed by
UCGOD Pharmaceutical Limited.
6, Oba T.T, Dada Avenue, Dental Bus Stop
Alonge Idi-Iroko Road, Ota Ogun State, Nigeria.

Manufactured by
Daily Sun Pharmaceutical Company Limited
Plot 3 & 4 Tomori industrial estate, off Idiroko road, Sango Ota, Ogun state.