

1. Name of medicinal product

Em-B-Plex Vitamin B complex tablets

2. Qualitative and quantitative composition

Each tablet contains:

Vitamin B1 (Thiamine HCL)

Vitamin B2 (Riboflavin)

Nicotinamide

Excipients with known effects:

For 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. Or as prescribed by a doctor

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.

Riboflavine (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.

Pyridoxine Hydrochloride (Vit B6): A water-soluble vitamin. Involved in carbohydrate and fat metabolism, but also important in haemoglobin formation.

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

6.2 Incompatibilities

None known

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 30°C . Protect from direct sunlight. Keep all medicines out of reach of children.

6.5 Nature and contents of container

PVC/Alu foil containing three blisters of 10 tablets each

6.6 Special precautions for disposal and other handling

None stated

7. Marketing authorization holder

Emzor Pharmaceutical Industries Limited'

Osolo Way, Oshodi/Isolo LGA, Aswani, Lagos state.

8. Marketing authorization number(s)

NA

9. Date of first authorization/renewal of authorization

NA

10. Date of revision of text

NA

