

1. Name of medicinal product

Envite multivitamin tablets.

2. Qualitative and quantitative composition

Each tablet contains:

- Cyproheptadine Hydrochloride
- Thiamine Nitrate BP
- Riboflavin BP
- Riboflavin BP

For full list of excipients, see section 6.1.

3. Pharmaceutical form

Tablet

4. Clinical particulars

4.1 Therapeutic indications

Envite (Multivitamin Tablets) is given as nutritional supplement and also given along with Antibiotic therapy. It is also prescribed / given during growth, during lactation, under stress, in fevers and other catabolic conditions such as hyperthyroidism.

4.2 Posology and method of administration

Posology:

1 tablet twice daily or as directed by a physician

Method of administration:

Oral

4.3 Contraindications

This preparation is contra indicated in those who are hypersensitive to any of the component of multivitamin Tablets.

4.4 Special warnings and precautions for use

When prescribing Multivitamin Tablets, as with all multi-vitamin preparations, allowance should be made for vitamins obtained from other sources. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Interactions of iron with tetracycline antibiotics (tetracycline, doxycycline, minocycline) and vitamin B6 and levodopa are known. Patients on any of these medications should seek medical advice before starting this product.

4.6 Pregnancy and lactation

It is safe to prescribe this preparation to pregnant woman but only under the supervision of medical practitioner.

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

Allergic reaction (difficulty breathing; closing of throat; swelling of lips, tongue, or face; or hives). Other, less serious side effects may be more likely to occur. Nausea, constipation, black stools, and diarrhea are among the most common.

4.9 Overdose

Treatment of over dosage is by supportive and symptomatic therapy. In the case of acute overdosage, according to the patient's condition, supportive therapy may include gastric lavage or emesis.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Emvite Multivitamin Tablet exert a stimulant effect at physical and psychological levels through the combined action of various substances on the basic metabolic processes.

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 Emvite Multivitamin Tablet 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.

5.3 Preclinical safety data

Not applicable

6. Pharmaceutical particulars

- Maize Starch BP
- Lactose BP
- Methyl Paraben BP
- Propyl Paraben BP
- Purified Water BP
- Sodium Starch Glycolate BP
- Colloidal Silicon Dioxide BP
- Purified Talc BP
- Magnesium Stearate BP
- Shellac Flakes BP
- Sucrose BP
- Titanium Dioxide BP
- Gelatin BP
- Polysorbate-80 BP
- Gum Acacia BP
- Colour Ponceau 4R Supra (E124)
- In-House Calcium Carbonate BP
- Purified Talc BP
- Isopropyl Alcohol BP
- PEG 6000 BP

7. Marketing authorization holder

6.2 Incompatibilities:

None stated.

6.3 Shelf Life:

24 months.

6.4 Special Precautions for storage:

Store below 30°C in a dry place. Protect from light.

6.5 Nature and contents of container:

Alu-Alu strip of 10 tablets each, such 3 strips are packed in a primary carton along with pack insert.

6.6 Special precautions for disposal and other handling:

No special requirements.

8. Marketing authorization number(s)

Emzor Pharmaceutical Industries Limited

Km 1 Flowergate Mixed Development Scheme, Sagamu/Benin Expressway, Makun, Sagamu, Ogun-State

9. Date of first authorization/renewal of authorization

N/A

10. Date of revision of text

N/A