

1. NAME OF THE MEDICINAL PRODUCT

Albevite Tablet.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Vitamin A Palmitate..... 2500IU
Vitamin D2 (Ergocalciferol)..... 250IU
Thiamine HCl (Vitamin B1)..... 600mcg
Vitamin C (Ascorbic Acid)..... 1300mcg

Excipients with known effect:

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

- Brown coloured Film coated tablet.

4. Clinical Particulars

4.1 Therapeutic indications

Albevite tablet is a palatable dietary supplement of multivitamin group required by children and adults for:

- Prevention of Vitamin deficiencies
- Growth
- Recovery from illness
- Loss of appetite
- Diarrhoea and infections
- After malaria infections
- Breast feeding

4.2 Posology and method of administration

For Adults, Children and the Elderly: One tablet three times a day, by oral administration.
Or as directed by the physician.

4.3 Contraindications

- Albevite Tablet is contraindicated in individuals with known hypersensitivity to the product or any of its components. When prescribing Albevite Tablet, as with all multi-vitamin preparations, allowance should be made for vitamins obtained from other sources.

4.4 Special warnings and precaution for use

Do not take Albevite tablet on an empty stomach. Do not exceed the stated dose. Keep out of the reach of children. If symptoms persist, consult your doctor.

4.5 Interactions with other medicinal products and other forms of interaction

None.

4.6 Pregnancy and Lactation

Albevite tablet may be administered during pregnancy and lactation at the recommendation of the physician.

4.7 Effects on ability to drive and use machines

None anticipated.

4.8 Undesirable effects

Adverse effects of Albevite Tablet are very rare. Mild nausea, vomiting and diarrhea may be observed.

4.9 Overdose

No cases of overdosage due to Albevite therapy have been reported. Any symptoms which may be observed due to the ingestion of large quantities of Albevite tablets will be due to the fat soluble vitamin content.

5. Pharmacological properties:

5.1 Pharmacodynamic properties

- Vitamin A palmitate

Vitamin A plays an essential role in the function of the retina, the growth and function of epithelial tissue, bone growth, reproduction and embryonic development.

- Vitamin D

Vitamin D is a regulator of both calcium and phosphate homeostasis.

- Thiamine hydrochloride (Vitamin B1)

Vitamin B1 is essential for proper carbohydrate metabolism and plays an essential role in the decarboxylation of alpha keto acids.

- Ascorbic acid (Vitamin C)

Ascorbic acid is a water soluble vitamin and a powerful antioxidant.

It is a cofactor in numerous biological processes, such as the metabolism of folic acid, amino acid oxidation and the absorption and transport of iron.

It is also required for the formation, maintenance and repair of intercellular cement material. Ascorbic acid is important in the defence against infection, the normal functioning of T-lymphocytes and for the effective phagocytic activity of leucocytes. It also protects cells against oxidation damage to essential molecules

5.2 Pharmacokinetic properties

Absorption

Vitamins A, B1, C, and D are well absorbed from the gastro-intestinal tract.

Distribution

The vitamins present in Albevite Tablet are widely distributed to all tissues in the body.

Metabolism and elimination

Vitamin A palmitate

Vitamin A palmitate is hydrolysed in the intestinal lumen to retinol which is then absorbed. Retinol circulates in the blood bound to retinol binding protein which protects it from glomerular filtration. The complex circulates to target tissues where the vitamin is released, permeates the cell and binds intracellularly to cellular retinol binding protein. Of the absorbed retinol 20 - 50 % is either conjugated or oxidised to various products and excreted over a matter of days in the urine and faeces, while the remainder is stored. This stored retinol is gradually metabolised by the liver and peripheral tissues.

Vitamin D

Vitamin D circulates in the blood associated with vitamin D binding protein. It is stored in fat deposits. Ergocalciferol is hydroxylated in the liver and gut to 25-hydroxy colecalciferol which is then further metabolised in the kidney to the active form 1,25-dihydroxycolecalciferol and other hydroxylated metabolites. Ergocalciferol and its metabolites are excreted largely in bile with eventual elimination in the faeces, with only small amounts of some of the metabolites appearing in the urine.

Thiamine hydrochloride (Vitamin B1)

Thiamine has a plasma half-life of 24 hours and is not stored to any great extent in the body. Excess ingested thiamine is excreted in the urine as either the free vitamin or as the metabolite, pyrimidine.

Ascorbic acid (Vitamin C)

Ascorbic acid reaches a maximum plasma concentration 4 hours following oral administration after which there is rapid urinary excretion. Following oral administration 60 % of the dose is excreted in 24 hours either as ascorbic acid or its metabolite dihydroascorbic acid.

Pharmacokinetics in Renal Impairment

There have been no specific studies of ALBEVITE Tablet in renal impairment.

Pharmacokinetics in the Elderly

Not appropriate.

5.3 Preclinical safety data

There is no pre-clinical data of relevance to a prescriber which is additional to that already included in other sections of the SmPC.

6. Pharmaceutical particulars

6.1 List of excipients

- Povidone
- Starch
- Sodium Propyl Paraben
- Lactose
- Ethanol
- HPMC
- Magnesium stearate
- Tween 80
- Caramel colour
- Talc
- Water

6.2 Incompatibilities

- None relevant known.

6.3 Shelf life

- 36 Months

6.4 Special precautions for storage

- Do not store above 30°C.
- Store in a cool dry place protected from light and out of reach of children.

6.5 Nature and contents of container<and special equipment for use, administration or implantation>

- Tin of 1000 tablets.

6.6 Special precautions for disposal<and other handling>

- None.

7 Applicant/Manufacturer

- Name: Alben Healthcare Industries Limited.
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