

1. NAME OF THE MEDICINAL PRODUCT

Alben Vitamin B complex Tablet.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Vitamin B1 (Thiamine HCl).....1mg
Vitamin B2 (Riboflavin).....1mg
Nicotinamide.....15mg

Excipients with known effect:

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

- Light Orange 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.

4.3 Contraindications

Known hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings and precaution for use

Do not take Alben Vitamin B complex 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

Alben Vitamin B complex 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 Alben Vitamin B complex tablet are very rare. Mild nausea, vomiting and diarrhea may be observed.

4.9 Overdose

No cases of over dosage due to Alben Vitamin B complex tablet therapy have been reported.

5. Pharmacological properties:

5.1 Pharmacodynamic properties

Nicotinamide is a vitamin. Riboflavin is a vitamin (B). Thiamine HCl is a vitamin (B). 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.

Riboflavin 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

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

- Gelatin
- Starch
- Magnesium stearate
- Talc

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

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