



National Agency for Food & Drug Administration & Control (NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

Alben Vitamin B Complex Syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml of syrup contains:

Thiamine Hydrochloride (Vitamin B1) B.P.....5mg

Riboflavin Sodium Phosphate (Vitamin B2) B.P.....2mg

Pyridoxine Hydrochloride (Vitamin B6) B.P.....2mg

Nicotinamide.....20mg

Excipients with known effect:

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

- Oral Liquid/Syrups.
- Yellow viscous syrup.

4. Clinical Particulars**4.1 Therapeutic indications**

Alben Vitamin B complex syrup is required in situations like:

- General deficiency states of the B-vitamins
- Growth
- Recovery from illness
- Breast feeding
- After malaria infection
- Loss of appetite
- Diarrhoea and infections

4.2 Posology and method of administration

For oral use only.

Children(above 1year): One teaspoonful (5ml) daily.

Adult: One tablespoonful (10ml) daily.

Or as directed by a Physician.

4.3 Contraindications

Hypersensitivity to the active substances, to any of the excipients listed in section 6.1.

4.4 Special warnings and precaution for use

The use of Alben Vitamin B complex syrup in patients with deficiency or increased requirement of vitamins B-complex should be accompanied by specific therapy for the primary illness.

Treatment with Alben Vitamin B complex syrup should be continued only until the deficiency is corrected or the need for supplementation exists.

Pyridoxine in Alben Vitamin B complex syrup may reduce the therapeutic effect of levodopa in Parkinson's disease.

Riboflavin in Alben Vitamin B complex syrup may color the urine yellow.

Keep out of reach of children.

Do not exceed recommended daily dose/amount.

4.5 Interactions with other medicinal products and other forms of interaction

Although the clinical importance is unknown, Thiamine reportedly may enhance the effect of neuromuscular blocking agents.

Nicotinamide reportedly potentiates the hypotensive effect of ganglionic blocking drugs

4.6 Pregnancy and Lactation

As with any other drug, if you are a pregnant or nursing baby, contact your healthcare professional before taking this drug.

4.7 Effects on ability to drive and use machines

The medication does not have any effect on ability to drive and use machines.

4.8 Undesirable effects

None known.

4.9 Overdose

B-Complex vitamins are water soluble and excess vitamins are expelled in urine.

Hence overdose is very rare.

In case of accidental overdose, discontinue use and seek professional assistance immediately.

5. Pharmacological properties:

5.1 Pharmacodynamic properties

Vitamin B Complex.

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

Riboflavin Sodium Phosphate (Vitamin 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 (Vitamin 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

- Sodium carboxymethylcellulose
- Sodium Methyl Paraben
- Sodium Propyl Paraben
- Sugar
- Citric acid
- Disodium Eddetate
- Sorbitol
- Glycerin
- Banana Flavour
- Demineralized water.

6.2 Incompatibilities

- Not Applicable.

6.3 Shelf life

36 Months

6.4 Special precautions for storage

- Store in a cool dry place below 30°C protected from light and out of reach of children.

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

Each cardboard box contains one bottle of 100ml PET bottle with metallic screw cap.

6.6 Special precautions for disposal<and other handling>

- None.

7. Applicant/Manufacturer

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