

1. NAME OF THE MEDICINAL PRODUCT

Vitamin B-Complex Syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:

Thiamine HCl ...5 mg

Pyridoxine HCl ...2 mg

Nicotinamide ...20 mg

Riboflavin ...2 mg

3. PHARMACEUTICAL FORM

Syrup

A Yellow coloured syrup with pleasant tasted

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Oral prophylactic and therapeutic treatment of vitamin B complex deficiency

4.2 Posology and method of administration

Prophylactic

Children

up to 1 year, One 5ml spoonful daily

up to 12 years, One 5ml spoonful twice daily

Adults and elderly

One 5ml spoonful three times daily

Therapeutic

Children

up to 1 year, One 5ml spoonful three times daily



up to 12 years, Two 5ml spoonfuls three times daily

Adults and elderly

Two to three 5ml spoonfuls three times daily

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

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard

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.

Riboflavin Sodium Phosphate (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.

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

Nicotinamide: White or almost white crystalline powder or colourless crystals. Freely soluble in water and in anhydrous ethanol, slightly soluble in methylene chloride.

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

Sugar, Sodium benzoate, Methyl paraben, Propyl paraben, Citric acid, Disodium EDTA, Glycerin, Mixed fruit flavors, Sodium Hydroxide, Sorbitol, Tartrazine and Purified water.

6.2 Incompatibilities

None

6.3 Shelf life

3 years



6.4 Special precautions for storage

Store between 4°C and 25°C. Protect from light

6.5 Nature and contents of container

150ml Glass bottle.

Cap White PP28 TE CR with EPE/PE/AL/PET Wad

None stated

6.6 Special precautions for disposal <and other handling

Medicines should not be disposed off via wastewater or household waste.
Ask your pharmacist how to dispose of medicines no longer required.
These measures will help to protect the environment.

7. APPLICANT/MANUFACTURER

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