

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

VIGRANON-B SYRUP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains

Thiamine Hydrochloride	5.00 mg
Riboflavin Sodium Phosphate	2.74 mg
Nicotinamide	20.00 mg
Pyridoxine Hydrochloride	2.00 mg
Dexpanthenol	3.00 mg

3. PHARMACEUTICAL FORM

Oral Solution

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

Or as prescribed by a doctor

4.3 Contraindications

Known sensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

No special warnings.

4.5 Interactions 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.

Riboflavine 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.

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

Pantothenol: The alcoholic analogue of D-pantothenic acid traditionally considered a B vitamin. It is a component of co-enzyme A, which is important in the metabolism of fat, carbohydrate and protein.

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

6.1 List of excipients

Disodium Edetate

Sorbitol Solution (non-crystallising)
Dilute Hydrochloric Acid
Methyl Hydroxybenzoate
Ethyl Hydroxybenzoate
Propyl Hydroxybenzoate
Butyl Hydroxybenzoate
Propylene Glycol
Soluble Orange Oil Flavour
Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months.

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

6.6 Instructions for use/handling

None stated

7 MARKETING AUTHORISATION HOLDER

Wallace Manufacturing Chemists Ltd.

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51-53 Stert Street
Abingdon
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United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 0400/5049R

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

05 March 1998

10 DATE OF REVISION OF THE TEXT

06/07/2015