



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

Registration & Regulatory Affairs (R & R) Directorate

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) TEMPLATE

1. NAME OF THE MEDICINAL PRODUCT

Avrobion Vitamin B- Complex Syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains

Thiamine Hydrochloride (Vitamin B ₁)	5mg
Riboflavin (Vitamin B ₂)	2mg
Nicotinamide	20mg
Pyridoxine Hydrochloride (Vitamin B ₆)	2mg

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

Children

1 year to 6 years: 2.5ml daily

7 to 12 years: 5ml daily

Adults and children above 12 years: 5ml spoonful two times daily

4.3 Contraindications

Known sensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Since the product contains Nicotinamide, it should be given cautiously in patients with a history of peptic ulcer disease and those with diabetes mellitus, gout or hepatic impairment.

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

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 (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.

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.

Thiamine Hydrochloride (Vit B1)

Thiamine is well absorbed from the gastro intestinal tract following oral administration, although the absorption of large doses is limited. It is also rapidly absorbed following intra muscular administration. It is widely distributed to most body tissues and appears in breast milk. Thiamine is not stored to any appreciable extent in the body and amounts in excess of the body's requirements are excreted in the urine as unchanged Thiamine or as metabolites.

Thiamine requirements are directly related to the carbohydrate intake and the metabolic rate. A daily dietary intake of 1 to 1.3mg of Thiamine is recommended for healthy men and 0.7 to 1mg for healthy women.

Riboflavine (Vit B2)

Riboflavine is readily absorbed from the gastro intestinal tract. Although Riboflavine is widely distributed to body tissues, little is stored in the body. Riboflavine is converted in the body to the coenzyme Flavine mononucleotide and then to another coenzyme Flavine adenine dinucleotide. About 60% of FMN and FAD are bound to plasma proteins. Riboflavine is excreted in urine, mainly as metabolites. As the dose increases, larger amounts are excreted unchanged. Riboflavine crosses the placenta and is distributed in breast milk.

The Riboflavine requirement is often related to the energy intake but it appears to be more closely related to the resting metabolic requirements. A daily dietary intake of about 1.3 to 1.8mg of Riboflavine is recommended.

Pyridoxine Hydrochloride (Vit B6)

Pyridoxine is readily absorbed from the gastro-intestinal tract following oral administration and is converted to the active forms pyridoxal phosphate and pyridoxamine phosphate. They are stored mainly in the liver where there is oxidation to 4-pyridoxic acid, which is excreted in the urine. Pyridoxine crosses the placenta and also appears in the breast milk.

For adults, the daily requirement of Pyridoxine is probably about 2mg and this amount is present in most normal diets. Meats, especially liver, cereals, eggs, fish and certain vegetables and fruits are good source of Pyridoxine.

Nicotinamide

Nicotinamide is absorbed readily from all portions of the intestinal tract and the vitamin is distributed to all tissues. The principal route of metabolism of Nicotinic acid and nicotinamide is by the formation of N—methylnicotinamide, which in turn is metabolized further. Small amounts of the unchanged vitamins appear in the urine following therapeutic doses of nicotinic acid and nicotinamide.

The daily adult requirement is probably about 15-20mg.

5.3 Preclinical safety data

None stated

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Methyl Hydroxybenzoate
Polysorbate 80
Glycerol
Orange Flavour

Deionised Water

6.2 Incompatibilities

None known

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store below 30°C. Protect from light.

6.5 Nature and contents of container

100ml Amber bottle with aluminium screw cap.

6.6 Special precautions for disposal and other handling

None stated

7. Applicant/manufacturer

Avro Pharma Limited

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