1. NAME OF THE MEDICINAL PRODUCT

Galways Vitamin B-Complex Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Thiamine Hydrochloride (Vitamin B1) 1mg

Riboflavin (Vitamin B2) 1mg

Nicotinamide 15mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

A yellow coloured tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Galways B-complex tablet is indicated in all cases where B vitamins supplementation is necessary and for the treatment and prevention of vitamin B deficiency states in pregnancy and disease. It contains essential vitamins that enhance vital metabolic processes in the body and aid proper utilization of energy from food. It also helps in the maintenance of the integrity of cells and replacement of worn out tissues.

4.2 Posology and method of administration

Adults: 1 tablet to be taken daily for the prevention of Vitamin B deficiency states or as directed by the physician.

For oral administration.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

Since Galways Vitamin B-Complex Tablet 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

Vitamin B-Complex Tablet may interact with certain antibiotic (such as chloramphenicol), phenytoin, ciprofloxacin, levodopa.

4.6 Fertility, pregnancy and lactation

Considered safe in the recommended dose

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

None known

4.9 Overdose

Overdosage of water-soluble vitamins would be rapidly excreted on cessation of dosage.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

Riboflavine (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.

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.

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. Smmall 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
Lactose
Povidone K.30
Crospovidone
Magnesium Stearate
FD & C Yellow No. 5

6.2 Incompatibilities

None known

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store below 30°C. Protect from light.

6.5 Nature and contents of container

It is packaged in blisters of 10 x 10's and packs of 100's and 1000's

6.6 Special precautions for disposal and other handling

No special requirements.

7. APPLICANT/ MANUFACTURER
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