SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

VITAKRIS (VITAMIN B-COMPLEX INJECTION 10 ML**)**

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Label Claim:

Each ml contains:

Thiamine Hydrochloride BP	10mg
Riboflavin Sod. Phosphate Eq. To Riboflavin	0.5 mg
Pyridoxine Hydrochloride BP	1mg
Nicotinamide BP	10mg
Dexpanthenol BP	1mg
Benzyl Alcohol BP (As Preservative)	2% v/v
Water for injection BP	Q.S

3. PHARMACEUTICAL FORM

Dosage Form: Solution for Injection

Description of Product: A Yellow coloured, clear solution filled in 10ml amber glass vial USP T-I.

4. Clinical particulars

4.1 Therapeutic indications

Vitamin B complex injection is a dietary supplement where a deficiency of vitamins exists.

4.2 Posology and method of administration

Deficiency can be reversed by thiamine in doses as small as 500 micrograms daily. A therapeutic dose of 1 to 2 mL daily is recommended.

4.3 Contraindications

Vitamin B complex should not be used in hypersensitivity to the product, glaucoma, gout, hypotension and ulcer disease.

4.4 Special warnings and precautions for use

If symptoms of peripheral sensory neuropathy (paraesthesia) occur, the dosage should be reviewed and treatment with the medicinal product discontinued, if necessary. Neuropathies have been observed under long-term administration (over 6-12 months) of daily dosages exceeding 50 mg vitamin B6 as well as in short-term administration (over 2 months) of more than 1 g vitamin B6 per day.

The Vitamin B Complex injection may be used in children and adolescents only in the case of compelling reasons.

4.5 Interaction with other medicinal products and other forms of interaction

Thiamine is inactivated by 5-fluorouracil as the latter competitively inhibits the phosphorylation of thiamine to thiamine pyrophosphate. Loop diuretics, e.g. furosemide that inhibit tubular reabsorption may cause increased excretion of thiamine in long-term therapy and, thus, lowering of the thiamine level. If taken simultaneously with L-dopa, vitamin B6 can lessen the dopa effect. The simultaneous administration of pyridoxine antagonists (e.g. isoniazide (INH), hydralazine, D-penicillamine or cycloserine) may increase the vitamin B6 requirement. Beverages containing sulphite (e.g. wine) enhance thiamine degradation.

It is possible the product to reduce the hyportensive effect of some adrenolytics and sympatholytics, as well as to decrease the hypnotic effect of barbiturates and glutethimide, due to presence of vitamin B1 in its composition. Chlorpromazine increases urine excretion of the vit. B2. Probenecid inhibits tubular excretion and reabsorption of the vit. B2, thus reducing its excretion in the urine. In concomitant administration with oral contraceptive agents, Rimicid, penicillamine, cycloserine, and thiosemicarbazones, the blood concentration of vit. B6 decreases.

4.6 Pregnancy and Lactation

Usage in pregnancy

There are only insufficient animal studies on the effect of this medicinal product on pregnancy, embryo-foetal, prenatal and postnatal development. The possible risk for human beings is not known. The treating physician should decide about the use of this product during pregnancy after carefully weighing the risk-to-benefit ratio.

Usage in nursing mothers

Vitamins B1, B6 are secreted into human breast milk. High concentrations of vitamin B6 can inhibit the production of breast milk. Data on the extent of secretion into breast milk from animal studies are not available. Therefore, the advantages of breast-feeding for the infant should be carefully weighed against the therapeutic benefit for the women in order to decide to either discontinue breast-feeding or therapy with Vitamin B Complex Injection.

4.7 Effects on ability to drive and use machines

Vitamin B Complex Injection does not affect the capability to drive a vehicle or to operate machinery.

4.8 Undesirable effects

The product is very well tolerated, however, in rare cases, itching, urticaria, and Quincke's edema may be observed in predisposed patients

4.9 Overdose

Thiamine has a broad therapeutic range. Very high doses (over 10 g) have a ganglion-blocking effect, similar to that of curare, and suppress the conduction of nerve impulses.

The toxic potential of vitamin B6 can be considered as very low. Long-term treatment (> 6-12 months) of a daily dosage > 50 mg vitamin B6 may, however, cause peripheral sensory neuropathy. Continuous intake of vitamin B6 at a daily dosage of more than 1 g over more than two months may produce neurotoxic effects. Neuropathies with ataxia and sensitivity disorders, cerebral convulsions with EEG changes as well as, in individual cases, hypochromic anaemia and seborrhoeic dermatitis have been described after administration of more than 2 g daily.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Vitamin B Complex Injection contains a combination of neurotropic active substances of the vitamin B complex. The vitamins thiamine (B1), pyridoxine (B6) and riboflavin contained play a particular role as coenzymes in the intermediary metabolism of the central and peripheral nervous system. Like all other vitamins, they are essential nutrients which the body cannot synthesize itself. Therapeutic supply of vitamins B1, B6 and riboflavin balances deficiencies due to inadequate nutritive vitamin intake and thus ensures the availability of the required quantities of coenzymes. Animal and clinical studies have indicated antinociceptive activity of vitamin B1, B6 and riboflavin.

5.2 Pharmacokinetic properties

Thiamine:

The elimination half-life is approx. 4 hours.

The human body can store approx. 30 mg thiamine. On account of the rapid metabolisation, the reserve capacity, at 4-10 days, is very limited.

Pyridoxine:

Approx. 40 to 150 mg can be stored, 1.7 to 3.6 mg is excreted in the urine per day.

5.3 Preclinical safety data

The toxicity of vitamins B1, B6, Nicotinamide and Riboflavin is very low. The data available to date do not suggest any potential risk for humans.

The literature available on the subject does not contain any findings indicating that vitamins B1, B6, Nicotinamide and Riboflavin have carcinogenic, mutagenic or teratogenic properties.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Along with the APIs the formulation contains followings excipients;

Sodium EDTA, Mono-thioglycerol, Polysorbate -80, Bezyl Alcohol.

6.2 Incompatibilities

It is not recommended to use Vitamin B Complex Injection together with other drugs in a 'mixed injection' or infusion. Vitamin B1 is completely degraded by sulphite-containing infusion solutions.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store below 30°C. The product should be used immediately after opening. Discard any unused portion.

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

Vitamin B Complex Injection is supplied in 10 ml amber glass vials, closed with a rubber stopper and sealed with an aluminium cap.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. APPLICANT/MANUFACTURER

NITIN LIFESCIENCES LIMITED

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