HANBET VITAMIN B COMPLEX INJECTION

1. NAME OF THE MEDICINAL PRODUCT

Hanbet Vitamin B Complex Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition
Each ml contains
Vitamin B1……..20mg
Vitamin B2……..2mg
Vitamin B6……..2mg
Nicotinamide……...50mg
Sodium D-pantothenate…1mg

3. PHARMACEUTICAL FORM

Injection

A clear yellow colored solution

4. CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

When the dietary intake is inadequate or in pronounced deficiency states, B-Complex vitamins are prescribed. In defined cases of clinical deficiency, parenteral administration is recommended for quick recovery of health and wellbeing.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

Posolog: The required quantity (1-2 ml) should be administered

Method of administration: Can be given by very slow I.V. or through a drip.

4.3 CONTRAINDICATIONS

No known contraindications have been indicated so far for the use of B-complex vitamins. However, a few persons are hypersensitive to thiamine. The most frequent reactions of hypersensitivity to vitamin B1 are anaphylaxis, dyspnoea or bronchospasm. A test dose may be given before vitamin B1 is administered parenterally.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Hypersensitivity to vitamin B1 should be excluded before parenteral therapy is instituted. Special care should be taken of patients with known allergic disposition. Pyridoxine can decrease efficacy in patients with levodopa, in patients with parkinsonism, should not be used for primary treatment of specific vitamin deficiency.

4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

Drug interactions with vitamins are rare and have not been reported. In fact, they are given as nutritional supplements during drug therapy especially when treating with antibiotics. During treatment with isoniazid, a deficiency state of vitamin B6 may occur and hence this vitamin is given during the period.

4.6 FERTILITY, PREGNANCY AND LACTATION

Not known

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Not known.

4.8 UNDESIRABLE EFFECTS

Rarely, hypersensitivity reactions to vitamin B1 may occur following parenteral administration of Estyplex-5 injection leading to skin rash, itching or even anaphylaxis involving nausea, vomiting, bronchospasm and circulatory collapse.

4.9 OVERDOSE:

Not known

5. PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES Vitamin B1 – Thiamine

Thiamine functions in all cells as the coenzyme cocarboxylase(thiamine pyrophosphate). It is the coenzyme for all enzymic decarboxylations of ketoacids. Thus, it functions in the oxidative decarboxylation of pyruvate to acetate, which in turn is combined with coenzyme A for entrance into the tricarboxylic cycle. This is an essential reaction for the utilization of carbohydrates to provide energy for body processes. When thiamine is deficient pyruvic and lactic acid accumulate in the blood and tissues and give rise to deficiency symptoms. In the cycle itself there are two steps at which CO2 is released under the reaction of the coenzyme. There are several other metabolic processes in which thiamine plays an essential role. Because its principle functions are concerned in energy metabolism, its requirement by the body bears a direct relation to the energy intake.

Thiamine is a cofactor in the metabolism of carbohydrates. This function is particularly important in nerve cell function. It also potentiates and mimics the effects of acetylcholine in the brain. These attributes explain its use in Alzheimer's Disease, being senescent forgetfulness and in epileptics taking Dilantin.

Vitamin B2 - Riboflavin-5-phosphate

Vitamin B2, also known as Riboflavin, is an easily absorbed, water-soluble micro nutrient with a key role in maintaining human health. Like the other B vitamins, riboflavin supports energy production by aiding in the metabolization of fats, carbohydrates and proteins. Vitamin B2 is also required for red blood cell formation and respiration, antibody production, and for regulating human growth and reproduction. Riboflavin is known to alleviate eye fatigue, prevent and treat cataracts, increase energy levels, and aid in boosting immune system functions. It also plays a key role in maintaining healthy hair, skin and nails, and in combination with vitamin B6, forms part of an effective treatment for carpal tunnel syndrome.

Vitamin B6 - Pyridoxine, Pyridoxal-5-phosphate

Vitamin B6 is an important nutrient that supports more vital bodily functions than any other vitamin. This is due to its role as a coenzyme involved in the metabolism of carbohydrates, fats, and proteins. Vitamin B6 is also responsible for the manufacture of hormones, red blood cells, neurotransmitters, enzymes and prostaglandins. Vitamin B6 is required for the production of serotonin, a brain neurotransmitter that controls our moods, appetite, sleep patterns, and sensitivity to pain. A deficiency of vitamin B6 can quickly lead to insomnia and a profound malfunctioning of the central nervous system.

Among its many benefits, vitamin B6 is recognized for helping to maintain healthy immune system functions, for protecting the heart from cholesterol deposits, and for preventing kidney stone formation. allergies, asthma and arthritis.

Vitamin B6 functions in several enzyme systems concerned in protein metabolism. In form of phosphorylated pyridoxal it serves as a coenzyme (codecarboxylase) for enzymes which decarboxylate several amino acids. As a phosphorylated pyridoxal, it also is a coenzyme for transaminases which catalyse the transfer of the amino group of glutaminic acid and other amino acids to keto acids. The vitamin also functions in a variety of other amino acid enzymes such as racemases, dehydrases, desulfhydrases, and hydroxylases. Pyridoxal phosphate is required for the synthesis of aminolevulinic acid, a precursor of heme. It is essential for the complete metabolism of tryptophan. Otherwise, the abnormal metabolite

xanthurenic acid is formed and excreted. The level of xanthurenic acid excretion has been used as an indicator of Vitamin B6 nutrition. Vitamin B6 is also concerned in some way with fat metabolism.

Nicotinamide:

Nicotinamide is a physiologically active compound. In the body, nicotinamide functions as a component of two coenzymes, (1) nicotinamide adenine dinucleotide (NAD) and (2) nicotinamide adenine dinucloetide phosphate (NADP). The enzymes containing NAD and NADP are more important links in a series of reactions associated with carbohydrates, proteins and lipid metabolism. They function in biological oxidation reduction systems by virtue of their ability to serve as hydrogen transfer agents. Although structurally nearly identical, they are not inter changeable.

NAD is specific for hydrogenesis, concerned with passing electrons onto O2 via the electron transport system in the tricarboxylic acid cycle. Here NAD serves as the electron acceptor in three of the four dehydrogenation steps. There are other important NAD containing dehydrogenases. NADP is specific for dehydrogenases concerned with biosynthesis reduction. It is contained in the alcohol-dehydrogenase system, the lactic acid dehydrogenase system, and others.

Pellegra, a disease caused by deficiency of this vitamin is characterized by a fiery red tongue, ulcers of the mouth, dermatitis, loss of appetite, and nausea amongst other symptoms.

Nicotinamide and nicotinic acid are relatively non toxic but massive doses result in vascular dilatation, or flushing with a burning sensation. Large chronic doses of nicotinic acid have also been used in attempts to lower serum cholesterol, but there nay be also decreased mobilization of fatty acids from the adipose tissue, hepatic injury, increased incidents of diabetes and peptic ulcers.

Prolonged administration of nicotinamide for hypercholesterolaemia has produced alterations in liver function and raised serum uric acid values.

5.2 PHARMACOKINETIC PROPERTIES

Thiamine:

Vitamin B1 is readily absorbed from the small and large intestine. It can be administered parentrerally.

Vitamin B1 is stored in the body. It is mainly concentrated in the liver, muscles, heart, kidneys and brain. The stores can be considerably reduced in a few days and so Vitamin B1 should be administered during acute illness when the food intake is poor.

Vitamin B1 is excreted in the urine, and a little is present in the faeces, though how much of this is the result of bacteriosynthesis in the intestines is not known. Breast milk also contains Vitamin B1.

The problem of identifying the early stages by any specific signs is an unsolved one for thiamine and several other of the B-vitamins. With respect to thiamine, the urinary excretion is linearly related to the intake except at low levels, and use is made of this fact in the diagnosis of the deficiency. A low level of excretion following a test dose is indicative of tissue deficiency.

Riboflavin:

Riboflavin is absorbed from the intestines. It is also absorbed when given parentrerally. Riboflavin is excreted in the urine and milk. Excess in the body is rapidly excreted in the urine to which it imparts a yellow colour.

Nicotinamide:

Nicotinamide is rapidly absorbed from the stomach, the small and the large intestine.

As an essential tissue coenzyme, nicotinamide is distributed in cells throughout the body.

The excretion of nicotinamide is mainly through the kidneys, partly as N-methyl nicotinamide and its glycine conjugate. The estimation of N-methyl nicotinamide in the urine is therefore used as a test of nicotinamide deficiency. There are

other end products of excretion which are not yet identified. After an intravenous injection, the urinary excretion is rapid, hence frequency small oral doses are therapeutically the most effective.

Pyridoxine: Absorption:
The absorption of Vitamin B6 from the intestine is rapid and occurs by diffusion mainly from the jejunum. It is also absorbed from the skin. If applied over a large area of skin, enough is absorbed to relieve all clinical and chemical signs of B6 deficiency.
The storage of Vitamin B6 in the body is usually sufficient to last for about 8 weeks.

All three compounds of Vitamin B6 are found in the urine after ingestion but 4-pyridoxic acid is quantitatively the most important excretion product. On a Vitamin B6 deficient diet, the excretion can be higher than the intake.

5.3 PRECLINICAL SAFETY DATA

Not Known

6. PHARMACEUTICAL PARTICULARS

6.1 INCOMPATIBILITIES

None

6.2 SHELF LIFE

36 months from the date of manufacturing.

6.3 SPECIAL PRECAUTIONS FOR STORAGE

Store below 30°C in a dry place, Protect from light and moisture.

6.4 NATURE AND CONTENTS OF CONTAINER:

Box of 10 or 100 colorless ampoules (glass type I).
Not all pack sizes may be marketed.

6.5 SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING

No special requirements.

7. Manufacturer:

Huazhong Pharmaceutical Co., Ltd.

No.118 Xianshan Road, Xiangyang City, Hubei Province, China