DCF Drugfield **PHARMACEUTICALS LIMITED**

SUMMARY OF PRODUCT CHARACTERISTICS

(SmPC)

Becomex® Injection

(VIT B1 5MG, VIT B2 2MG, VIT B6 2MG, NICOTINAMIDE 20MG/ML)

1. NAME OF THE MEDICINAL PRODUCT

Becomex® (VIT B1 5MG, VIT B2 2MG, VIT B6 2MG, NICOTINAMIDE 20MG/ML) Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains Vitamin B1 5mg, Vitamin B2 2mg, Vitamin B6 2mg, Nicotinamide 20mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Injection

4. Clinical particulars

4.1 Therapeutic indications

Vitamin B complex is needed for the proper functioning of almost every process in the body.

Energy Production

Vitamin B1 is needed to help convert carbohydrates into glucose. Vitamin B2 and Vitamin B6 are needed at a cellular level to convert glucose into energy.

Vitamins B6 is essential for amino acid metabolism and is required for the formation of hemoglobin

A deficiency in any of these B vitamins can lead to decreased energy production, lethargy and Fatigue.

Healthy Nervous System

The Vitamin B complex is essential for the healthy functioning of the nervous system.

Vitamin B1 and Vitamin B6 are essential for the regulation and correct functioning of the entire nervous system including brain function.

Good digestion

The Vitamin B Complex is essential for correct digestion, production of Hydrochloric acid and to assist in the breakdown of fats, proteins and carbohydrate. Especially vital for good digestion are Vitamin B1, Vitamin B2, and Vitamin B6.

A deficiency in any of these B Vitamins can lead to impaired digestion and deficiency of essential nutrients

Posology and method of administration

Posology

Important Dosage and Administration Instructions

A therapeutic dose of 1 to 2ml daily is recommended.

There is only limited experience with therapy in children and adolescents.

Method of Administration

Parenteral form may be administered by intramuscular (i.m) or slow intravenous (i.v) injection.

4.2 Contraindications

Hypersensitivity to the active substances or to any of the excipients

4.3 Special warnings and precautions for use

Short-term parenteral vitamin B12 administration may temporarily impair the diagnosis of funicular myelosis or pernicious anemia. 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. Becomex® Injection may be used in children and adolescents only in the case of compelling reasons.

4.4 Interaction with other medicinal products and other forms ofinteraction

Clinically Significant Drug Interactions with Becomex® injection

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.

Pregnancy and Lactation

Pregnancy

Risk Summary

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.

Lactation

Risk Summary

Vitamins B1, B6 and B12 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 treatment.

Pediatrics

Becomex® Injection may be used in children and adolescents only in the case of compelling reasons.

4.5 Effects on ability to drive and use machines

None known

4.6 Undesirable effects

In the following, the undesirable effects are classified by organ system and frequency. The assessment of undesirable effects is based on the following frequency grouping:
Very common (1/10)
Common (1/100, <1/10)
Uncommon (1/1,000, <1/100)
Rare (1/10,000, < 1/1,000)
Very rare (< 1/10,000)
Unknown (frequency not estimable on the basis of the data available)

Nervous system disorders:
Unknown: Long-term intake (> 6-12 months) of a daily dosage > 50 mg vitamin B6may cause peripheral sensory neuropathy.

Gastrointestinal disorders:
Unknown: Gastrointestinal complaints such as nausea, vomiting, diarrhoea and abdominal pain.

Immune system disorders:
Very rare: Hypersensitivity reactions such as sweating, tachycardia and skin reactions like itching and urticaria, as well as anaphylaxis.

Skin and subcutaneous tissue disorders:
Unknown: Allergic reactions, eczematous skin alterations and a benign form of acne have been observed after high-dose vitamin B12.
General disorders and administration site conditions: Unknown: Injection-site reactions.

4.7 Overdose

Vitamin B1: 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.
Vitamin B6: 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.
Vitamin B12: Allergic reactions, eczematous skin alterations and a benign form of acne have been observed after high-dose parenteral administration

Treatment should be discontinued

5. PHARMACOLOGICAL PROPERTIES

Pharmacodynamics

Becomex ampoules contain a combination of neurotropic active substances of the vitamin B complex. The vitamins thiamine (B1), pyridoxine (B6) and cobalamin (B12) 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 synthesise itself. Therapeutic supply of vitamins B1, B6 and B12 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, B6and B12.

Nicotinamide is converted in the body to the enzymes nicotinamide adenine dinucleotide and nicotinamide adenine dinucleotide phosphate which are involved in electron transfer reactions in the respiratory chain.

5.1 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.

Cobalamin:

Vitamin B12 is stored predominantly in the liver, the daily requirement is 1µg. The turnover rate is 2.5 µg B12 per day, or 0.05% of the stored quantity. Vitamin B12 is mainly secreted into bile and largely reabsorbed during the enterohepatic circulation.

Nicotinamide is readily absorbed from the gastro-intestinal tract following oral administration and widely distributed in the body tissues. The main route of metabolism is conversion to n-methylnicotinamide and the 2-pyridone and 4pyridone derivatives; nicotinuric acid is also formed. Small amounts of nicotinamide are excreted unchanged in urine following therapeutic doses; however the amount excreted unchanged is increased with larger doses.

5.2 Preclinical safety data

The toxicity of vitamins B1, B6 and B12 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 and B12 have carcinogenic, mutagenic or teratogenic properties.

Chronic toxicity: In animals, very high doses of vitamin B1 cause bradycardia. Other symptoms are blockade of vegetative ganglia and motor end plates. The oral administration of 150–200 mg of vitamin B6/kg body weight/day over a period of 100-107 days caused ataxia, muscular asthenia, disorders of balance, as well as degenerative changes of axons and myelin sheaths in

dogs. Animal studies also showed incidences of convulsions and impaired coordination after high doses of vitamin B6.

Mutagenic and tumorigenic potential: Mutagenic effects of vitamin B1 and vitamin B6are not to be expected under the conditions of clinical use. There are no long-term animal studies available on the tumorigenic potential of thiamine and vitamin B6.

Reproduction toxicity: Thiamine is transported actively to the foetus. Concentrations in the foetus and the newborn exceed maternal concentrations of vitamin B1. Systematic investigations on human embryonal and foetal development in connection with the use of vitamin B1 at doses exceeding the stated daily requirements are not available. Vitamin B6 is insufficiently investigated in animal studies. An embryotoxicity study in rats gave no indications of a teratogenic potential. In male rats the administration of very high doses of vitamin B6 induced damage to spermatogenesis.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Riboflavin -5- Phosphate Sodium, Pyridoxine Hydrochloride, Nicotinamide, D-Panthenol, Benzyl Alcohol, Sodium Formaldehyde Sulphoxylate, Water for Injection to

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store below 30^0C. Protect from light and moisture.

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

Becomex® Injection is a clear Yellow solution free from foreign matter contained in 10ml amber colored vial bottle and grey stopper with silver seal.

6.6 Special precautions for disposal and other handling

No special requirements.

7. APPLICANT/MANUFACTURER

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