1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC)

1. Name of the medicinal product

Vitamin B Complex Injection 2ml

2. Qualitative and quantitative composition

-Vitamin B1 (Thiamine hydrochloride)---------- 10mg
-Vitamin B2 (Riboflavin)----------1mg
-Vitamin B6(Pyridoxine hydroxide)----------1mg
-Nicotinamide---------15mg
- Sodium D-Pantothenate----------0.5mg

3. Pharmaceutical form

Solution for injection.

4. Clinical particulars

4.1 Therapeutic indications

Vitamin B Complex Injection is indicated for correction and management of the known symptoms and diseases ofthe deficiency conditions of the respective individual vitamins in the complex ie Thiamine, Ribofloxacin, Pyridoxine, Nicotinamide and Sodium D-Pantothenate. lt is prescribed by doctors and used by many people for an immediate boost inenergy. Injections are generally more effective than tablets because the digestive systems, stomach acids and enzymesattack the molecular structure of B vitamins when consumed orally.ltis also indicated in conditions requiring increased vitamin activity eg. pre and post operative treatment, fever, urns, pregnancy, prolonged wasting diseases, alchoholisom etc.

4.2 Posology and method of administration

Usual dose of adult is 0.25 to 2 ml by intra muscular (IM) or slow intravenous (IV) administration daily. Duration oftherapy depends on response and severity of the condition. Higher concentration for IV administration may be diluted using parenteral infusion solution..

4.3 Contraindications

This medication should not be used in patients sensitive to any of the ingredients. lt is contra-indicated in heamophilliacs and patients with mechanical obstruction of the digestive tract.

4.4 Special warnings and precautions for use

There has not been any report of adverse reaction warranting dis-use of the B-vitaminsin pregnancylactation, but as usual, drug use in pregnancy and lactation should be under the supervision of a healthcarepractitioner and benefits should be weighed against the potential side effects of the drug.

4.5 Interaction with other medicinal products and other forms of interaction
These classifications are only a guideline. The relevance of a particular drug interaction to a specific individual is difficult to determine. Always consult your healthcare provider before starting or stopping any medication.

Major	Highly clinically significant. Avoid combinations; the risk of the interaction outweighs the benefit.
Moderate	Moderately clinically significant. Usually avoid combinations; use it only under special circumstances.
Minor	Minimally clinically significant. Minimize risk; assess risk and consider an alternative drug, take steps to circumvent the interaction risk and/or institute a monitoring plan.
Unknown	No interaction information available.

4.6 Pregnancy and lactation
There has not been any report of adverse reaction warranting dis-use of the B-vitamins in pregnancy & lactation, but as usual, drug use in pregnancy and lactation should be under the supervision of a healthcare practitioner and benefits should be weighed against the potential side effects of the drug.

4.7 Effects on ability to drive and use machines
None.

4.8 Undesirable effects
Mild transcient diarrhea, polycythenia vera, peripheral vascular thrombosis , itching, transitoryexanthema, feeling of the entire body.
Rarely, anaphylactic shock may be associated with long term administration of large doses.

4.9 Overdose
NA.

5. Pharmacological properties
5.1 Pharmacodynamic properties
Vitamin B2 (Riboflavin) is bound to plasma proteins.A little is stored in organs such as liver and kidneys, andamounts in excess of the body's requirements are excreted in the urine.
Vitamin B1(thiamine) is fundamentally associated with carbohydrate metabolism.By combining with the pyrophosphoric acid in nucleated cells, particularly in the liver, kidneys and white blood cells it is converted inthe body to its pyrophosphate which acts as coenzyme in such reactions as the decarboxylation of alpha-ketoacids, particularly of pyruvate and alpha-keto-glutarate.In the presence of Vitamin B1 deficiency pyruvic andlactic acids accumulate in the tissues.

5.2 Pharmacokinetic properties
The name vitamin B complex is used to refer to a group of chemically widely differing, but therapeutically related substancesused in the management of metabolic dleficiency states in the body.The major vitamins that make up vitamin B complexinclude:

1. Thiamine (Vitamin B1)-whose deficiency is mostly due to inadequate dietary intake. Severe deficiency may result to a condition called—Beri Beri". Dry beri beri is characterized by peripheral neuropathy, muscle wasting, weakness andparalysis while wet beri beri is characterized by cardiac failure and oedema.
2. Riboflavin (Vitamin B2)-deficiency may be due to reduced dietary intake or reduced absorbtion due to liver disease,alchoholism, chronic infection, probenicid therapy. Deficiency state may lead to a condition called ariboflavinosis characterized by angular stomatitis,painful red tongue and lips, sore throat, cheilosis, seborrthic ketosis of the nose andano-genital region. Also ocular symptoms including itching and burring of the eyes, photophobia and corneal vascularisation.
3.PYRIDOXINE (Vitamin B6) : is involved principally in amino acid metabolism, but it is also involved in carbohydrate andfat metabolism. lt is also required for the fomation of hemoglobin. Pyridoxine deficiency in the adult leads to the development of peripheral neuritis. Deficiency in children also affects the CNS.lt is used in the treatment of sideroblasticanemia in certain metabolic disorders.
4. NICOTINAMIDE: This is converted to coenzymes nicotinamide adenine dinucleotide(NAD) and nicotinamide adeninedinucleotide phosphate(NADP) which are involved in the electron transfer reaction in the respiratory chain. Its deficiency develops when the dietary intake is inadequate and leads to deficiency syndrome characterized by skinlesions on the area exposed to sunlight with hyperpigmetation and hyperkeratinization.
As nicotinic acid it inhibits the synthesis of cholesterol and triglyceride and may be useful in hyper-lipidemia.
5. SODIUM-D-PANTHOTHENATE:This is the alchoholic anaiogue of D-pantothenic acid.It is an integral member of theB-complex vitamins and is effective in cases involving intestinal atony.B-complex vitamins are all water soluble and areeasily absorbed and transported in the body after oral or parenteral administration.Peak effect is seen within a few hoursafter 1M/IV administration. Thiamine is 90% bond to protein(album). A binding protein called thiamine binding protein,believed to be hormone regulated is responsible for tissue distribution of thiamine. Excretion of the B complex is principally through the urine as acid metabolism of the components.

5.3 Preclinical safety data
None stated.

6. Pharmaceutical particulars
6.1 List of excipients
Disodium edetate, Polysorbate 80, Sodium Bicarbonate, Water for injection.

6.2 Incompatibilities
None.

6.3 Shelf life
36 months.

6.4 Special precautions for storage
Store in a place below 25°C. Protect from light. Do not freeze.

6.5 Nature and contents of container
2ml ampoule.

6.6 Special precautions for disposal and other handling
None stated.

7. Manufacturer's name

TianJin KingYork Group Hubei Tianyao Pharmaceutical Co. Ltd

8. Applicant

Pemason Pharmaceuticals Ltd
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