

1. NAME OF THE MEDICINAL PRODUCT

Brand Name: --

Generic Name: Vitamin B-Complex Injection

Composition:

Each 10ml Vial contains:

Vitamin B1 BP..... 25 mg

Vitamin B2 BP2 mg

Vitamin B6 BP..... 2.5 mg

Nicotinamide BP50 mg

D-Panthenol USP5 mg

Benzyl Alcohol BP2%v/v

Water for Injections BP q.s.

Pharmaceutical form: Liquid Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Sr. No	Material	Specification	Rationale	Composition	Overage %	Qty/ml	Qty/Batch Size(1050 lit)
1	Vitamin B1	BP	Active ingredients	25mg/10ml	35	3.38 mg	3.720 kg
2	Vitamin B2	BP	Active ingredients	2mg/10ml	15	0.23 mg	0.347 kg
3	Vitamin B6	BP	Active ingredients	2.5mg/10ml	49	0.38 mg	0.393 kg
4	Niacinamide	BP	Active ingredients	50mg/10ml	12	5.6 mg	5.890 kg
5	D panthenol	USP	Active ingredients	5mg/10ml	14	0.57 mg	0.605 kg
6	Benzyl alcohol	BP	Preservative	0.2mg/10ml		0.02 ml	21.00 lit
7	Tween 80	BP	Surfactant	0.08mg/10ml		0.008 mg	8.400 kg
8	Disodium EDTA	BP	Chelating Agent	0.01mg/10ml		0.001 mg	1.050 kg
9	Sodium Chloride	BP	Tonicity	0.009mg/10 ml		0.0009 mg	0.945 kg
10	Sodium Hydroxide	BP	For PH adjustment	10.05 mg/10 ml		1.05 mg	0.105 kg
11	Water for injections	BP	Vehicle	QS		Qs to 1 ml	Qs to1050 lit

Where,
BP = British Pharmacopoeia
USP = United State Pharmacopoeia.
Q.S: = Quantity Sufficient

3. PHARMACEUTICAL FORM

Liquid Injection

4. Clinical particulars

4.1 Therapeutic indications

For treatment of vitamin B-complex deficiency states and during convalescence from illness.

4.2 Posology and method of administration

Posology

One vial once daily by intramuscular or slow intravenous injection or as advised by physician.

4.3 Contraindications

Hypersensitivity to vitamin B complex and any other ingredients of Injection.

4.4 Interaction with other medicinal products and other forms of interaction

It is possible the product to reduce the hypotensive 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. Vit. B6 reduces the antiparkinsonian effect of L-Dopa. In concomitant administration with oral contraceptive agents, Rimicid, penicillamine, cycloserine, and thiosemicarbazones, the blood concentration of vit. B6 decreases

4.5 Pregnancy and Lactation

It is safe to use in pregnancy and lactation.

4.6 Effects on ability to drive and use machines

Not Applicable

4.7 Undesirable effects

Rarely, hypersensitivity reactions to vitamin B1 may occur leading to skin rash and

itching.

4.8 Overdose

Symptoms include hypotension, tachycardia, myocardial ischaemia dysrhythmias and coma.

Treatment

Supportive measures including intravenous fluids are also indicated. If hypotension is present, an attempt should be made to raise the blood pressure without increasing the tachycardia. Adrenaline should therefore be avoided

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties Pharmacotherapeutic group: treatment of vitamin B-complex deficiency,

Thiamine Hydrochloride BP : A11DA01

Riboflavin Sodium Phosphate BP: A11HA04

Pyridoxine Hydrochloride BP: A11HA02

Nicotinamide BP: A11HA01

D-Panthenol USP: A11HA30

Mechanism of action:

Riboflavin is bound to plasma proteins. A little is stored in organs such as liver and kidneys, and amounts in excess of the body's requirements are excreted in the urine.

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 in the body to its pyrophosphate which acts as coenzyme in such reactions as the decarboxylation of alpha-keto acids, particularly of pyruvate and alpha-keto-glutarate. In the presence of thiamine deficiency pyruvic and lactic acids accumulate in the tissues.

5.2 Pharmacokinetic properties

The mode of administration of **Vitamin B-Complex Injection** is by injectable route, thus the bioavailability of this product is considered 100% as it is directly provided into systemic circulation.

5.3 Preclinical safety data

No more information available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl Alcohol	BP
Polysorbate 80	BP
Sodium chloride	BP
Sodium Hydroxide	BP
Disodium EDTA	BP
Water for Injections	BP

6.2 Incompatibilities

The dosage form being small volume injectable, dosage device or reconstitution is not required. Hence, Incompatibility with the same is not applicable.

Shelf life

24 months

6.3 Special precautions for storage

Store in a cool and dry place below 30°C and keep away from light.

6.4 Nature and contents of container <and special equipment for use, administration or implantation>

(10 x10 ml) amber colour glass vials packed in printed carton along with Pack insert

6.5 Special precautions for disposal <and other handling>

No special requirements

7. <APPLICANT >

Malven Medics Int'l Co.Ltd.

No.4, Ligali Street Ogudu, Lagos Nigeria