SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)

KABIPLEX INJECTION
[Vitamin B-Complex]

Submitted by

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Summary Product Characteristics

1. **Name of the proprietary product: KABIPLEX INJECTION**

Name of the nonproprietary International Product: Vitamin B-Complex Injection

Route of Administration: Liquid Injection

2. **Qualitative and Quantitative composition:**

Sr. No.	Ingredients	Specification	Label Claim	Overage %	Quantity/ ml (mg)	Quantity/ vial (mg)	Reason for Inclusion
1.	Thiamine Hydrochloride	BP	25 mg	35.00	2.5	33.75	Active
2.	Riboflavin Sodium Phosphate	BP	2 mg	15.00	0.2	2.3	Active
3.	Pyridoxine Hydrochloride	BP	2.5 mg	49.00	0.25	3.725	Active
4.	Nicotinamide	BP	50 mg	12.00	5	56.00	Active
5.	D-Panthenol	USP	5 mg	14.00	0.5	5.7	Active
6.	Benzyl Alcohol	BP	2% v/v	--	2% v/v	2% v/v	Preservative
7.	Polysorbate 80	BP	0.8 %w/v	--	0.8 %w/v	0.8 %w/v	Surfactant
8.	Sodium chloride	BP	0.09 %w/v	--	0.09%w/v	0.09%w/v	pH Adjustment
9.	Sodium Hydroxide	BP		--	--	--	Buffering Agent
10.	Disodium EDTA	BP	0.1% w/v	--	0.1%w/v	0.1%w/v	Chelating Agent
11.	Water for Injections	BP	q.s.	--	q.s.to 1 ml	q.s. to 10 ml	Solvent

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:
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 Nervit Injection.

4.4 Special warnings and precautions for use

Not to be used for newborn babies or premature infants.

WARNINGS:
Anaphylactogenesis may occur with parenteral thiamine. Use with caution. An intradermal test dose is recommended prior to administration in patients suspected of being sensitive to the drug.

PRECAUTIONS:
The usual precautions for parenteral administration should be observed. Do not inject if precipitation occurs. Inject slowly by the intravenous route. High concentrations should be diluted using Normal Saline Injection when given intravenously.

4.5 Interaction with other medicinal products and other forms of interaction:
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. 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

4.6 Pregnancy and Lactation:
It is safe to use in pregnancy and lactation.

4.7 Effects on the ability to drive and use machines
Not Applicable

4.8 Undesirable effects:
Rarely, hypersensitivity reactions to vitamin B1 may occur leading to skin rash and itching.

4.9 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 Particulars:
5.1 Pharmacodynamic properties
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 **Kabiplex (VITAMIN B-COMPLEX INJECTION)** is by injectable route, thus the bioavailablity of this product is considered 100% as it is directly provided into systemic circulation.

5.3 Pre-clinical Safety:
No more information available.

6. Pharmaceutical Particulars:

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.

6.3 Shelf Life:
24 months.

6.4 Special Precautions for storage:
Store at 30^0C. Protect from light.
Keep out of reach of children.

6.5 Nature and contents of container:
10 ml amber colour glass vial, packed in Primary carton along with Pack insert.

6.6 Special precautions for disposal and other handling:
None.

7. Manufactured by
PHARMAX INDIA PVT. LTD.,
9, KURLA INDUSTRIAL ESTATE,
NETAJI PALKAR ROAD,
GHATKOPAR
(WEST),MAHARASHTRA, MUMBAI-
400 086, INDIA

8. Marketing Authorization Holder:
KATARI PHARM & STORES LIMITED, G.G. 5,
WARRI STREET, KADUNA, KADUNA
STATENIGERIA

9. Date of first Authorization /renewal of the authorization: ---

10. Date of revision of text: