PRODUCT NAME:	VITAMIN B-COMPLEX INJECTION

MODULE 1 - ADMINISTRATIVE AND PRODUCT INFORMATION

1.3.1 SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)

1. Name of drug product

VITAMIN B-COMPLEX INJECTION

1.1 (Trade) name of product

VITAMIN B-COMPLEX INJECTION

1.2 Strength

Composition:

Each 10 ml vial contains:

Vitamin B1 BP .....25 mg

Vitamin B2 BP .....2 mg

Vitamin B6 BP .....2.5 mg

Nicotinamide BP .....50 mg

D Panthenol BP .....5 mg

Phenol BP..... % w/v

(As preservative)

Water for injection BP..... Q.S

1.3 Pharmaceutical Dosage Form

Small Volume Parenteral

PRODUCT NAME:	VITAMIN B-COMPLEX INJECTION

MODULE 1 - ADMINISTRATIVE AND PRODUCT INFORMATION

2. Qualitative & Quantitative Composition

2.1 Qualitative Declaration

Composition:

Each 10 ml vial contains:

Vitamin B1 BP .....25 mg

Vitamin B2 BP .....2 mg

Vitamin B6 BP .....2.5 mg

Nicotinamide BP .....50 mg

D Panthenol BP .....5 mg

Phenol BP..... % w/v

(As preservative)

Water for injection BP..... Q.S

2.2 Quantitative Declaration

Batch Formula:

Batch Size: 1,00,000 Vial

Sr. No.	Ingredients	Grade	Rationale	Label Claim	Over ages	Quantity /Unit (mg)	Quantity/ Batch (Kg)
1.	Vitamin B1	BP	Active	25 mg	---	25.00	2.50
2.	Vitamin B2	BP	Active	2 mg	---	2.00	0.20
3.	Vitamin B6	BP	Active	2.5 mg	---	2.50	0.25
4.	Nicotinamide	BP	Active	50 mg	---	50.00	5.00
5.	D Panthenol	BP	Active	5 mg	---	5.00	0.50
6.	Phenol	BP	Preservative	0.5 % w/v	---	5.00	0.50
7.	Water for injection	BP	Solvent	---	---	Q.S	Q.S

PRODUCT NAME:	VITAMIN B-COMPLEX INJECTION

MODULE 1 - ADMINISTRATIVE AND PRODUCT INFORMATION

3. Pharmaceutical Dosage Form

Small Volume Parenteral

4. Clinical Particulars

4.1 Therapeutic Indications

VITAMIN B-COMPLEX INJECTION is indicated in adults and children for rapid therapy of severe depletion or malabsorption of the water soluble vitamins B complex.

- Particularly in alcoholism
- After acute infections
- Post-operatively
- In psychiatric states.

4.2 Posology and Method of Administration

VITAMIN B-COMPLEX INJECTION is also available as an Intravenous High Potency, Solution for Injection. Therefore before administration ensure that both the Summary of Product Characteristics and ampoule labels refer to the INTRAMUSCULAR injection.

Posology

Adults and elderly: The contents of one pair of ampoules (7ml) twice daily for up to 7 days.

Paediatric population: VITAMIN B-COMPLEX INJECTION Intramuscular High Potency is rarely indicated for administration to children, however suitable doses are as follows:

Under 6 years	quarter of the adult dose
6-10 years	third of the adult dose
10-14 years	half to two thirds of the adult dose
14 years and over	as for the adult dose

Method of administration

The contents of one ampoule number 1 and one ampoule number 2 of VITAMIN B-COMPLEX INJECTION Intramuscular High Potency (total 7 ml) are drawn up into a syringe to mix them just before use, then injected slowly high into the gluteal muscle, 5cm below the iliac crest.

MODULE 1 - ADMINISTRATIVE AND PRODUCT INFORMATION

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

4.4 Special Warnings and Precautions for Use

Although potentially serious allergic adverse reactions such as anaphylactic shock may occur rarely during, or shortly after, parenteral administration of VITAMIN B-COMPLEX INJECTION Intramuscular, such rare occurrence of serious allergic reactions should not preclude the use of VITAMIN B-COMPLEX INJECTION Intramuscular in patients who need treatment by this route of administration. Initial warning signs of a reaction to VITAMIN B-COMPLEX INJECTION Intramuscular are sneezing or mild asthma, and those treating patients need to note that the administration of further injections to such patients may give rise to anaphylactic shock. Facilities for treating anaphylactic reactions should be available whenever VITAMIN B-COMPLEX INJECTION Intramuscular High Potency is administered.

This medicine is for injection into a muscle only and should not be given by any other route

Care should be taken to ensure that the route of administration used (intramuscular or intravenous) is that intended – reports of unintentional administration by the wrong route have been received; these incidents have not been associated with serious adverse reactions.

In common with all parenteral products each ampoule should be visually inspected prior to administration and should not be used if particulates are present.

This medicinal product contains approximately 67 mg sodium per 7 ml dose (1 pair of ampoules), equivalent to 3.4% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

This medicine contains approximately 139 mg benzyl alcohol in each 7 ml dose (1 pair of ampoules) which is equivalent to 19.9 mg/ml:

• Benzyl alcohol may cause allergic reactions.

• Intravenous administration of benzyl alcohol has been associated with serious adverse events and death in neonates ("gasping syndrome"). The minimum amount of benzyl alcohol at which toxicity may occur is not known.

• Increased risk due to accumulation in young children.

• High volumes should be used with caution and only if necessary, especially in subjects with liver or kidney impairment because of the risk of accumulation and toxicity (metabolic acidosis)

MODULE 1 - ADMINISTRATIVE AND PRODUCT INFORMATION

4.5 Interaction with Other Drugs, Other Forms of Interactions

The content of pyridoxine may interfere with the effects of concurrent levodopa therapy.

4.6 Fertility, pregnancy and lactation

No adverse effects have been reported at recommended doses when used as clinically indicated.

Animal studies are insufficient with respect to reproductive toxicity (see section 5.3). The potential risk for humans is unknown.

Caution should be exercised when prescribing to pregnant women.

4.7 Effects on ability to drive and operate machine

None known.

4.8 Undesirable effects

Adverse reactions reported as possibly associated to VITAMIN B-COMPLEX INJECTION are presented in the following table by MedDRA System Organ Class (SOC), Preferred Term and frequency. The following frequency categories are used:

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), including isolated reports.

Post-marketing adverse reactions are reported voluntarily from a population with an unknown rate of exposure. Therefore it is not possible to estimate the true incidence of adverse reactions and the frequency is “unknown”.

Tabulated summary of adverse reactions

SYSTEM ORGAN CLASS (SOC)	FREQUENCY	ADVERSE REACTION
Immune system disorders	Unknown	Hypersensitivity (including anaphylaxis, rash and urticaria)
Nervous system disorders	Unknown	Paraesthesia
Vascular disorders	Unknown	Hypotension
General disorders and	Unknown	Injection site reactions (including pain and

administration site conditions		swelling)

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

4.9 Overdose

Not applicable.

5. Pharmacological properties

5.1 Pharmacodynamic properties

VITAMIN B-COMPLEX INJECTION Intramuscular High Potency contains vitamins B1, B2, B6, nicotinamide.

Pharmacotherapeutic group: Vitamin B-complex, ATC code: A11EB

5.2 Pharmacokinetic properties

None supplied.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the Summary of Product Characteristics.

6. Pharmaceutical particulars

6.1 List of excipients

Phenol

Water for injection

6.2 Incompatibilities

Not Applicable.

PRODUCT NAME:	VITAMIN B-COMPLEX INJECTION

MODULE 1 - ADMINISTRATIVE AND PRODUCT INFORMATION

6.3 Shelf-Life

24 Months

6.3 Special Precautions for Storage

Do not store above 25°C. Keep vials in the outer carton in order to protect from light.

6.4 Nature and Contents of Container

10 ml solution filled in a clear glass vial. Such a 50-vial packed in a carton along with pack insert.

7. Marketing authorisation holder

E-GLOBA PHARM GMBH LIMITED

6, AMICHI STREET, COKER VILLAGE, LAGOS

8. Marketing authorisation number(s)

9. Date of first authorisation/renewal of the authorisation

10. Date of revision of the text