

Summary of Product Characteristics (SmPC)**Product Name: Vitamin B Complex Injection****Summary Product Characteristics****1. Name of the proprietary product:****Name of the nonproprietary International Product:** Vitamin B-Complex Injection**Route of Administration:** 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

Summary of Product Characteristics (SmPC)

Product Name: Vitamin B Complex Injection

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 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 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

4.6 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.

Summary of Product Characteristics (SmPC)

Product Name: Vitamin B Complex Injection

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 **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 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 below 30°C in cool and dry place. Protect from light.

6.5 Nature and contents of container:

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

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Product Name: Vitamin B Complex Injection

6.6 Special precautions for disposal and other handling:

None.

7. Marketing Authorization Holder:

DOM DIKE PHARMACEUTICAL COMPANY
LIMITED

14c Ilodibe street awada layout onitsha Anambra state

MANUFACTURER
PHARMAX (INDIA) PVT LTD, 9
KURLA INDUSTRIAL ESTATE
PALKAR ROAD,
LBS MARG, GHATKOPAR (W)
MUMBAI-400086, INDIA.

8. Marketing Authorization Number: ---

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

10. Date of revision of text:

For I.M./I.V. use only

VITAMIN B-COMPLEX INJECTION

5 x 10 Vials x 10 ml

VITAMIN B-COMPLEX INJECTION

For I.M./I.V. use only

VITAMIN B-COMPLEX
INJECTION

Composition:
Each 10ml Vial Contains:
Vitamin B1 BP 25 mg
Vitamin B2 BP 2 mg
Vitamin B6 BP 2.5 mg
Nicotinamide BP 50 mg
D-Panthenol USP 5 mg
Benzyl Alcohol BP 2% v/v
Water for injections BP q.s.

Dosage: - As directed by the Physician.
Storage: - Store in a dark place below 30°C.
Protect from light, heat and moisture.
Keep all medicines out of reach of children.
Do not use the solution if particulate matter is seen.

VITAMIN B-COMPLEX
INJECTION

Mfg. Lic. No.: 882
Batch No. :
Mfg. Date :
Exp. Date :


Manufactured by :
PharmaX India Pvt. Ltd.
PharmaX India Pvt. Ltd.
Narayan Nagar, Ghatalgaon (W),
Mumbai - 400 086, INDIA.

Marketed by:
**DOM DKE PHARMACEUTICAL**
14C, Indira street, awade layout
onitsha Anambra state, Nigeria.

PharmaX
INDIA PVT LTD

Date : 07.08.2024

Name of Product : VITAMIN B-COMPLEX INJECTION

Dimensions : L-261 X W-128 x H-59mm

Board :

Finishing : Aqua Varnish

Shelf life :

5 x 10 Vials x 10 ml

VITAMIN B-COMPLEX INJECTION

For I.M./I.V. use only

VITAMIN B-COMPLEX
INJECTION

Composition:
Each 10ml Vial Contains:
Vitamin B1 BP 25 mg
Vitamin B2 BP 2 mg
Vitamin B6 BP 2.5 mg
Nicotinamide BP 50 mg
D-Panthenol USP 5 mg
Benzyl Alcohol BP 2% v/v
Water for injections BP q.s.

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5 x 10 Vials x 10 ml

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For I.M./I.V. use only

VITAMIN B-COMPLEX
INJECTION

Mfg. Lic. No.: 882
Batch No. :
Mfg. Date :
Exp. Date :


Manufactured by :
PharmaX India Pvt. Ltd.
PharmaX India Pvt. Ltd.
Narayan Nagar, Ghatalgaon (W),
Mumbai - 400 086, INDIA.

Marketed by:
**DOM DKE PHARMACEUTICAL**
14C, Indira street, awade layout
onitsha Anambra state, Nigeria.

VITAMIN B-COMPLEX INJECTION

For I.M./I.V. use only

10 x 10ml

10 x 10ml

10 x 10ml

10 x 10ml

VITAMIN B-COMPLEX INJECTION

VITAMIN B-COMPLEX INJECTION

Composition:
Each 10ml Vial Contains:

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Vitamin B2	BP	2 mg
Vitamin B6	BP	2.5 mg
Nicotinamide	BP	50 mg
D-Panthenol	USP	5 mg
Benzyl Alcohol	BP	2% v/v
Water for Injections	BP	q.s.

Storage: As directed by the Physician.
Dosage: Store in a dark place below 30°C.
Protect from light, heat and moisture.
Keep all medicines out of reach of children.
Do not use the solution if particulate matter is seen.

Composition:
Each 10ml Vial Contains:

Dosage : As directed by the Physician.

Keep all medicines out of reach of children.

Do not use the solution if particulate matter is seen.

PharmaX
INDIA PVT LTD
Date : 07.08.2024
Name of Product : VITAMIN B-COMPLEX INJECTION
Dimensions : L-125mm X W-51mm X H-56mm
Board :
Finishing : Aqua Varnish
Shelf life :

10 x 10ml

For I.M./I.V. use only

Manufactured by :
Pharma India Pvt. Ltd
9, Kuria Industrial Estate,
Narayan Nagar, Ghatakopar (W),
Mumbai - 400 086, INDIA.

Marketed by:
DOM DIKE PHARMAC
COMPANY LIMITED
14c Ilodibe street awa
onitsha Anambra state

Product Name : VITAMIN B-COMPLEX INJECTION		Date :- 07/08/2024
		GSM :- 60
Leaflet SIZE	90 x 125	Paper :- MAPLITHO
Leaflet Size After Folding :- 45 x 31		Printing :- FRONT / BACK
Folding:- L : 1 H: 2		Colour :- BLACK

90x125mm Front

90x125mm Back

VITAMIN B-COMPLEX INJECTION

For I.M./I.V. use only

Composition:

Each 10ml Vial Contains:

Vitamin B1	BP	25 mg
Vitamin B2	BP	2 mg
Vitamin B6	BP	2.5 mg
Nicotinamide	BP	50 mg
D-Panthenol	USP	5 mg
Benzyl Alcohol	BP	2% v/v
Water for Injections	BP	q.s.

Pharmacology

Vitamins belonging to group B possess a biology activity in low concentrations and exert a regulating effect on the cell function. They participate in number of enzyme systems and in such a manner in the regulation of carbohydrate, protein and lipid metabolism. After the conforming to pyrophosphate Vitamin B1 participates in the carbohydrate, and protein metabolism, as well as in synthesis of nucleic acids as a co-enzyme. It influences the neural impulse conduction in the synapse.

Vitamin B2 improves the carbohydrate and lipid metabolism, and is related to aminoacid metabolism. It participates in iron and porphyrin exchange, in hemoglobin synthesis and in the tissue respiration.

Vitamin B6 is a part of following enzymes: decarboxylase and transaminase. It participates in histamine, free fatty acid, and aminoacid metabolism. The vitamin plays a role in the normal functioning of the central and peripheral nervous system, skin, and gastrointestinal tract. Niacinamide is included in co-dehydrases, participating in the hydrogen transport and in oxygenation-restoration processes, necessary for the tissue respiration.

Indications

Vitamin B-complex Injection is indicated in following diseases, manifesting with a vitamin B deficiency: neuritis; alcohol, toxic, and post infectious polyneuritis; diabetic polyneuropathy; neuralgia; sciatica; central spastic conditions; myasthenia; paresthesia; atherosclerosis; Wernicke's encephalopathy; vegetative neurosis; dermatitis; neurodermatitis; psoriasis; lupus erythematosus; furunculosis; stomatitis; cheilitis; glossitis; colitis; hepatitis; chronic alcohol abuse; asthenia; anemia; intoxications.

Prophylactically in infants, pregnant women, chronic diarrhea, Beriberi, Chronic Alcoholics.

In neurological and cardiovascular disorders, hyperemesis gravidarum, chronic anorexia obstinate constipation.

Contra-indications

Vitamin B-complex Injection should not be used in hypersensitivity to any of the vitamins, containing in the preparation, as well as in patients with 2-nd or 3-rd degree arterial hypertension.

WARNING

Liver function tests and plasma glucose should be frequently monitored. Do not use if any particle or precipitate appears.

PRECAUTIONS

Vitamin B-Complex Injection must be injected slowly. Because of in vitro incompatibility the preparation should not be used simultaneously (in the same syringe) with following preparations: Benzilpenicillin and oxacyllin (the antibiotic precipitates and is inactivated), macrolides (insoluble sedimentation is formed); Chloramphenicol (precipitation); Vitamin B12 (cobalt ions destruct vitamin B2); Vitamin C (inactivates vitamin B6). The preparation can be used in pregnant and nursing women.

Interactions

Adverse Effects

If the injection is taken for a prolonged period and in high doses it can cause edema, pain in the joints, reduction in protein metabolism and depression. If the patient is hypersensitive to any of the vitamins in the injection it can cause anaphylactic reaction.

Dosage & Administration

The solution for injection is applied parenterally-intramuscularly or (rarely) intravenously in dose 1-2 mL daily or each second day, within 5-10 days.

OVER DOSAGE

The side effects caused by Vitamin B-Complex overdose can be avoided by following appropriate vitamin B complex dosage prescribed by the physician.

Storage : Store in a dark place below 30°C. Protect from light, heat and moisture. Keep all medicines out of reach of children.

Do not use the solution if particulate matter is seen.

Presentation

10 Vials x 10ml

Manufactured by :

PharmaX India Pvt. Ltd.

9, Kurla Industrial Estate,
Narayan Nagar, Ghatkopar (W),
Mumbai - 400 086. INDIA.



Marketed by:
**DOM DIKE PHARMACEUTICAL
COMPANY LIMITED**
14c Ilodibe street awada layout
onitsha Anambra state, Nigeria.

07.08.2024
SIZE 55X23

For I.M./I.V. use only
VITAMIN B-COMPLEX INJECTION
Each 10ml Vial Contains: Mfg. Lic. No. : 682
Vitamin B1 BP 25mg Batch No. :
Vitamin B2 BP 2mg Mfg. Date :
Vitamin B6 BP 2.5mg Exp. Date :
Nicotinamide BP 50mg
D-Panthenol USP 5mg
Benzyl Alcohol BP 2%v/v
Water for Injections BP qs
Marketed by:
DOM DIKE PHARMACEUTICAL
COMPANY LIMITED
14c Ilodibe street awada layout
onitsha Anambra state, Nigeria.
Manufactured by :
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Vitamin B2 BP 2mg Mfg. Date :
Vitamin B6 BP 2.5mg Exp. Date :
Nicotinamide BP 50mg
D-Panthenol USP 5mg
Benzyl Alcohol BP 2%v/v
Water for Injections BP qs
Marketed by:
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