

**Summary Product Characteristics (SPC):**

Enclosed

**1. Name of the medicinal product: GALAXY'S NEUROCARE INJECTION**  
(Methylcobalamin, Niacinamide, Pyridoxine HCl & D-Panthenol Injection)

**2. Qualitative and Quantitative composition:**

Sr. No	Ingredients	Specification	Label Claim	Qty/2ml (mg)	Over ages	Reason for inclusion
<b>ACTIVE</b>						
1.	Methylcobalamin	IH	1000.0 mcg	1.40	40.0%	Medicament
2.	Pyridoxine HCl	USP	100.0 mg	115.0	15.0%	Medicament
3.	Niacinamide	USP	100.0 mg	115.0	15.0%	Medicament
4.	D-Panthenol	USP	50.0 mg	55.0	10.0%	Medicament
<b>EXCIPIENTS</b>						
3.	Benzyl alcohol	USP	--	0.04 ml	--	Preservative
4.	Sodium chloride	BP	--	10.0		Tonicity
5.	Disodium EDTA	BP	--	2.00	--	Chelating agent
6.	Sodium dihydrogen orthophosphate	BP	--	2.00	--	Buffering agent
7.	Propylene Glycol	BP	--	40.00	--	Solvent
8.	Sodium Hydroxide	BP	--	4.00	--	PH Adjustment
9.	Monothioglycerol	USP	--	0.002 ml	--	Antioxidant.
10.	Water for Injection	USP	--	q.s. to 2 ml	--	Solvent

Where, USP- United State Pharmacopoeia, BP- British Pharmacopoeia; IH-Inhouse  
q.s.: Quantity Sufficient

Note: - Quantity of active ingredients to be taken by consideration of their Assay and water contents

**3. Pharmaceutical Form:** Solution for injection

**4. Clinical Particulars:**

**4.1 Therapeutic Indications**

1. Peripheral Neuropathy of Various aetiology
2. Compression Neuropathy
3. Diabetic Neuropathy
4. Other Neurological Disorders: Parkinson's Disease, Alzheimer's Disease, Epilepsy, Facial Palsy
5. Disturbed Cognitive functions and memory.
6. Sleep wake disorders.
7. In trauma, Megaloblastic Anaemia caused by Vitamin B12 deficiency, Cancer, Hyperhomocysteinemia.

#### **4.2 Posology and method of administration**

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

#### **4.3 Contraindications**

Known hypersensitivity to any of the active constituents or excipients.

#### **4.4 Special warnings and precautions for use**

Not to be used in newly born or premature infants.

Additional precautions that need to be considered are as follows

(1) Methylcobalamin is susceptible to photolysis. It should be used promptly after the package is opened, and caution should be taken so as not to expose the ampoules to direct light.

(2) Intramuscular administration

In intramuscular administration, caution should be exercised by following the instructions mentioned below to avoid adverse effects on tissues or nerves.

a) Avoid repeated injection at the same site.

b) Do not inject in densely innervated site.

c) If insertion of the injection needle causes intense pain or if blood flows back into the syringe, withdraw the needle immediately and inject at a different site.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

Loop diuretics, e.g. furosemide that inhibit tubular reabsorption may cause increased excretion of thiamine in long-term therapy and, thus, lowering of the thiamine level. If taken simultaneously with L-dopa, vitamin B6 can lessen the dopa effect.

The simultaneous administration of pyridoxine antagonists (e.g. isoniazide (INH), hydralazine, D-penicillamine or cycloserine) may increase the Pyridoxine hydrochloride requirement.

#### **4.6 Pregnancy and Lactation**

The usual precautions should be observed when administering drugs during pregnancy, especially in the first trimester.

However animal studies are insufficient with respect to effects on pregnancy/ and-or/ embryonal/foetal development/ and-or/ parturition/ and-or/ postnatal development. The potential risk for humans is unknown. Kindly consult a physician before use

#### **4.7 Effects on the ability to drive and use machines**

Not Applicable

#### **4.8 Undesirable effects**

In the following, the undesirable effects are classified by organ system and frequency. The assessment of undesirable effects is based on the following frequency grouping:

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)

Unknown (frequency not on the basis of the data available)

##### **Nervous system disorders:**

Unknown: Long-term intake (> 6-12 months) of a daily dosage > 50 mg vitamin B6 may cause peripheral sensory neuropathy.

**Gastrointestinal disorders:**

Unknown: Gastrointestinal complaints such as nausea, vomiting, diarrhoea and abdominal pain.

**Immune system disorders:**

Very rare: Hypersensitivity reactions such as sweating, tachycardia and skin reactions like itching and urticaria, as well as anaphylaxis.

**Skin and subcutaneous tissue disorders:**

Unknown: Allergic reactions, eczematous skin alterations and a benign form of acne have been observed after high-dose vitamin B12.

**General disorders and administration site conditions:**

Unknown: Injection-site reactions.

**4.9 Overdose**

Treatment of vitamin overdose usually consists of withdrawal of the vitamin and other measures as clinically indicated.

**5. Pharmacological Particulars:****5.1 Pharmacodynamic properties**

**Pharmacotherapeutic group:** Vitamin B-complex, plain

**ATC code:** A11EA

**Methylcobalamin:**

- Methylcobalamin is a Neurotropic and acts as a growth promoter for nerve cells, a property which helps to regenerate Central and Peripheral nervous tissue damaged in disorder such as diabetic peripheral neuropathy.
- Methylcobalamin acts as a methyl donor for the synthesis of Lecithin, a major component of the Myelin sheath.
- Methylcobalamin facilitates methylation of t-RNA which play a fundamental role in protein synthesis and stimulates methionine synthesis and helps to restore normal levels of RNA in nerve cells.
- Methylcobalamin acts as a co-factor in the enzyme methionine synthase which regenerates methionine thus generating an increased supply of S-Adenosyl Methionine (SAME) and SAME protects from Neurotoxicity.
- Methylcobalamin normalizes Nerve cell conduction by healing the damaged nerve cells and restores delayed synaptic transmission and diminished neurotransmitters to normal.
- Methylcobalamin improves the excitability of the nerve fibres and thus improves the neurotransmission.

**Pyridoxine Hydrochloride:**

Perhaps the most important of Vitamin Bs for a healthy body. Vitamin B6 is a master vitamin in the processing of amino acid - the building blocks of all proteins and some hormones. It plays a role in the multiplication of all cells and the production of red blood cells and the immune system. It also acts as co-enzymes for substances that regulate and stimulate brain and central nervous system responses.

- Boost immunity
- Protects against cancer and cell abnormalities
- Helps control diabetes.

**Niacinamide:**

Vitamin B3 is required for cell respiration, helps in the release of energy and metabolism of carbohydrates, fats, and proteins, proper circulation and healthy skin, functioning of the nervous system, and normal secretion of bile and stomach fluids. It is used in treating schizophrenia and other mental illnesses and a memory-enhancer. Nicotinic acid given in drug dosage improves the blood cholesterol profile. Reports confirm that with sufficient supply of Niacinamide, there is improvement in mental alertness.

A deficiency may cause pellagra and is characterized by bilateral dermatitis, diarrhoea, dizziness, fatigue, halitosis, headaches, indigestion, insomnia, limb pains, loss of appetite, low blood sugar, muscular weakness, skin eruptions, and inflammation.

**5.2 Pharmacokinetic properties****Pyridoxine:**

Approx. 40 to 150 mg can be stored; 1.7 to 3.6 mg is excreted in the urine per day.

**Methylcobalamin:**

Vitamin B12 is stored predominantly in the liver; the daily requirement is 1 µg. The turnover rate is 2.5 µgB12 per day, or 0.05% of the stored quantity. Vitamin B12 is mainly secreted into bile and largely reabsorbed during the enterohepatic circulation.

**5.3 Pre-clinical Safety:**

No more information available.

**6. Pharmaceutical Particulars:****6.1 List of Excipients:**

Benzyl alcohol	USP
Sodium chloride	BP
Disodium EDTA	BP
Sodium dihydrogen orthophosphate	BP
Propylene Glycol	BP
Sodium Hydroxide	BP
Monothioglycerol	USP
Water for Injection	USP

**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 a dry place. Protect from light. Do not freeze.

**6.5 Nature and contents of container:**

2 ml amber coloured glass ampoule, 5 such ampoules are packed in a tray, such tray is packed in a Carton along with the Pack Insert.

**6.6 Special precautions for disposal and other handling:**

Not Applicable.

**7. Marketing Authorization Holder:**

**GALAXY PHARMACEUTICAL LTD**

1 st Floor, Doctors' Park, 3 rd Parklands

Avenue, P.O. BOX 39107-00623

Kenya

**8. Marketing Authorization Number: --**

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

**10. Date of revision of text: November 2019**