



GALAXY'S NEUROCARE PLUS
(Methylcobalamin, Pregabalin, Folic acid, Pyridoxine hydrochloride and Alpha Lipoic acid Capsules)

1.4.1 PRESCRIBING INFORMATION (SPC)

Proprietary Name

GALAXYS NEUROCARE CAPSULES

Approved Generic Name

Methylcobalamin, Pregabalin, Folic acid, Pyridoxine hydrochloride and Alpha Lipoic acid Capsules

Qualitative & Quantity formula:

Each soft gelatin capsule contains:

Methylcobalamin	750mcg
Pregabalin	75mg
Folic acid	BP 1.5mg
Pyridoxine hydrochloride	BP 3mg
Alpha Lipoic acid	USP 100mg
Excipients	q.s



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Quantitative Declaration

Batch Size: 2, 00,000 capsules

S.No	Ingredients	Label claim mg/cap	Over-age in %	Specification ¹	Quantity per capsule (mg/cap)	Quantity per Batch (kg/Batch)	Function
FILL MATERIALS							
1.	Methylcobalamin	750mcg	50	IHS	1.125	225.000gm	Vitamin supplement
2.	Pregabalin	75.0mg	10	IHS	82.500	16.500	Dietary supplement
3.	Folic acid	1.5mg	50	BP	2.250	0.450	Antioxidant
4.	Pyridoxine hydrochlorid	3mg	10	BP	3.300	0.660	Vitamin supplement
5.	Alpha Lipoic Acid	100 mg	20	USP	120.000	24.000	Vitamin supplement
6.	Refined Soya oil	--	--	BP	360.625	72.125	Diluent
7.	Lecithin	--	--	USP	10.000	2.000	Emollient
8.	Hydrogenated Vegetable	--	--	BP	10.000	2.000	Suspending agent
9.	Butylated Hydroxy Anisole	--	--	BP	0.100	20.000gm	Suspending agent
10.	Butylated Hydroxy Toluene	--	--	BP	0.100	20.000gm	Antioxidant
11.	Calcium hydrogen	--	--	BP	110.000	22.000gm	Diluent
SHELL MATERIALS²							
12.	Gelatin ³	--	--	BP	211.283	42.257	Gelling agent
13.	Glycerol	--	--	BP	75.494	15.099	Plasticizer
14.	Liquid Sorbitol (Non-	--	--	BP	25.141	5.028	Plasticizer
15.	Methyl Hydroxybenzoat	--	--	BP	1.227	0.245	Preservative
16.	Propyl Hydroxy	--	--	BP	0.124	0.025	Preservative
17.	Titanium dioxide	--	--	BP	1.137	0.227	Colouring Agent
18.	Pantone colour shade	--	--	IH	0.595	0.119	Colouring Agent
19.	Purified Water	--	--	BP	35.000	7.000	Diluent

Abbreviation:

BP: British Pharmacopoeia

USP: United States Pharmacopoeia

IH: In-House



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¹ Current pharmacopoeial monographs are implied

² In the batch formula excess material is added to compensate process loss. Process loss due to Cooking tank wastages, Placebo wastages, Service tank/spreader box retention & Net Wastage

³ Gelatin is derived from Bovine bones free from skulls, spinal cord and vertebrae. Country of origin – India

Pharmaceutical Form:

Softgel Capsules

Red coloured oblong shaped opaque soft gelatin containing pale yellow coloured oily mass

Clinical Particulars:

Therapeutic indications:

Galaxy's NEUROCARE PLUS is indicated for Peripheral Neuropathy, Diabetic Neuropathy, Drug induced Neuropathy, Fibromyalgia, Adjunctive therapy for adult patients with partial onset seizures.

Recommended route of administration: Oral

Posology and method of administration

Dosage: As directed by the Physician

Method of administration: Oral

Contraindications:

GALAXY'S NEUROCARE is contraindicated if the user is known to be hypersensitivity to any of the ingredient in the formulation.

Special warning and precautions for use

Patients with diabetes taking hypoglycaemic agents require monitoring since supplements can reduce the need for insulin and oral agents in diabetic patients.

Pediatric Use:

It is not recommended for use in children below 18 years due to insufficient data on safety and efficacy.

General use:

Protect from light. Prolonged daily dose administration over 25,000 Units vitamin A should be under close supervision. Blood level assays are not a direct measure of liver storage. Liver storage should be adequate before discontinuing therapy. Single vitamin A deficiency is rare. Multiple vitamin deficiency is expected in any dietary deficiency.

Interaction with other medicinal products and other forms of Interactions

Methylcobalamin

Drugs such as metformin, proton pump inhibitors and H2 receptor antagonist can interfere with the absorption of methylcobalamin

Folic Acid

Drugs that can interfere with folic acid metabolism include cimetidine, antacids, and sulfasalazine. Folic acid can increase the metabolism of anti-seizure medications, including carbamazepine and Phenobarbital. Phenytoin and valproic acid appear to interfere with folate absorption



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Pyridoxine Hydrochloride

Many drugs may alter the metabolism or bioavailability of pyridoxine, including isoniazid, penicillamine and oral contraceptives, which may increase the requirements for pyridoxine. Pyridoxine hydrochloride may reduce the effect of levodopa, a drug used in the treatment of Parkinson's disease unless a dopa decarboxylase inhibitor is also given.

Pregabalin

Concurrent use of pregabalin with oxycodone, lorazepam and ethanol may increase the central nervous system effects e.g. depression.

Pregnancy and lactation

Methylcobalamin

Methylcobalamin is not recommended in pregnancy and lactation.

Alpha lipoic acid

Not enough is known about the use of alpha-lipoic acid during pregnancy and breast feeding.

Folic acid

Pregnancy: It is suggested that all women capable of becoming pregnant consume folate in order to reduce the risk of the fetus developing a neural tube defect. Folic acid supplementation in higher than suggested doses is categorized as U.S. Food and Drug Administration (FDA) Pregnancy Category C.

Breast feeding: Folic acid is present in the breast milk and is likely safe to use during breastfeeding under the supervision of a qualified healthcare provider.

Pyridoxine

Vitamin B6 is likely safe during pregnancy when used orally in doses not exceeding the recommended dietary allowance (RDA).

Vitamin B6 is likely safe during lactation when used orally in doses not exceeding the RDA.

Effects on ability to drive and use machines

None reported.

Undesirable effects

Ingredients present in Neurocare Plus are generally well tolerated but mild side effects like nausea, headache etc might be observed.

Overdose and special antidotes

No data available

Pharmacological Properties :

Pharmacodynamics Properties

Methylcobalamin

Methylcobalamin is one of the coenzyme forms of Vitamin B12, which is water-soluble vitamin in the body. Its deficiency leads to damage the nervous system. This causes a wide range of neurological disorders.

Methylcobalamin is required for the conversion of homocysteine to methionine and its derivative S-adenosyl methionine.

Alpha lipoic Acid

Alpha-lipoic acid is a potent antioxidant in both fat- and water-soluble mediums. Furthermore, its antioxidant activity extends to both its oxidized and reduced forms.



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Dihydrolipoic acid is capable of directly regenerating ascorbic acid from dehydroascorbic acid and indirectly regenerating vitamin E. Alpha lipoic also increases intracellular glutathione and coenzyme Q10 levels. Alpha lipoic acid prevents protein glycosylation and inhibition of the enzyme aldose reductase, the latter of which subsequently inhibits conversion of glucose and galactose to sorbitol. These mechanism account for its benefits in preventing diabetic complications

Folic Acid

Folic acid's primary mechanisms of action are through its role as a methyl donor in a range of metabolic and nervous system biochemical processes, as well as being necessary for DNA synthesis. Serine reacts with tetrahydrofolate, forming 5,10-methylenetetrahydrofolate, the folate derivative involved in DNA synthesis. A methyl group is donated to cobalamin (B12) by 5-methyltetrahydrofolate, forming methylcobalamin. With the help of the enzyme methionine synthase, Methylcobalamin donates a methyl group to the amino acid metabolite homocysteine, converting it to the amino acid methionine.

Pyridoxine Hydrochloride

Pyridoxine depend enzymes are involved in a number of reactions such as decarboxylation of amino acids to yield amines, many of which are important neurotransmitters and hormones, transamination of amino acids to keto-acids, which are then oxidized and used as metabolic fuel, phosphorolytic cleavage of glycogen (from liver and muscle) to glucose-1-phosphate, formation of alpha aminolevulinic acid, a precursor to heme, decarboxylation of phosphatidylserine to phosphatidylethanolamine in substance and synthesis, as a co-factor in a variety of reactions involving side-chain cleavage, including cystathionine synthase and cystathionase

Pregabalin

Pregabalin is a structural analog of the inhibitory neurotransmitter gamma-aminobutyric acid (GABA). It has been reported that its action presents the function of modulating the release of many excitatory neurotransmitters such as glutamate, norepinephrine, and calcitonin gene related peptide. This modulation can cause an inhibitory modulation of overexcited neurons allowing them to get back to a normal state, including the decrease on the hyper excitability caused by tissue damage. The neurotransmitter modulation allows pregabalin to present antiallodynic, anxiolytic and anticonvulsant activity.

Pharmacokinetic Properties

Methylcobalamin

After oral administration, the peak plasma concentration can be achieved after three hours. The vitamin is eliminated in the urine as unchanged drug.

Alpha lipoic Acid

Alpha lipoic acid appears to be readily absorbed via the intestines from an oral dose and converts easily to its reduced form, dihydrolipoic acid (DHLA), in many tissues of the body (Alpha- lipoic Acid Monograph, Altern Med Rev 2006; 11(3):232-37). About 20- 40% of oral alpha lipoic acid is absorbed from a dose of 200 mg. Alpha lipoic acid is excreted via renal elimination and has shown to cross the blood brain barrier



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Folic Acid

Human pharmacokinetic studies indicate folic acid has very high bioavailability, with large oral doses of folic acid substantially raising plasma levels in healthy subjects in a time- and dose-dependent manner. Subsequent to high-dose oral administration of folic acid (ranging from 25-1,000 mg/day), red blood cell (RBC) folate levels remain elevated for periods in excess of 40 days following discontinuation of the supplement. Folic acid is poorly transported to the brain and rapidly cleared from the central nervous system.

The primary methods of elimination of absorbed folic acid are fecal (through bile) and urinary

Pyridoxine Hydrochloride

Pyridoxine and its vitamers are absorbed in the upper small intestine by simple diffusion and transported to the liver for biotransformation into the active coenzyme pyridoxine 5 phosphate, which is then exported from the liver bound to albumin. Uptake into tissue is by extracellular de-phosphorylation, followed by metabolic trapping intracellularly as pyridoxine 5 phosphate

Pregabalin

After oral administration, Pregabalin is rapidly absorbed in GIT. The Cmax can be achieved within one hour after administration. The oral bioavailability is about 90%. The rate of absorption is influenced by food intake. Pregabalin is not bound to plasma proteins. The VSS of Pregabalin is 0.56L/kg. About 98% of the administered Pregabalin is excreted via the urine as unchanged drug.

Pharmaceutical Particulars :

List of excipients:

S.No	Ingredients	Specification	Function
1	Hydrogenated vegetable oil	BP	Suspending agent
2	Butylated Hydroxy Anisole	BP	Antioxidant
3	Butylated Hydroxy Toluene	BP	Antioxidant
4	Lecithin	USP	Emollient
5	Refined Soya Oil	BP	Diluent
6	Calcium hydrogen Phosphate	BP	Diluent
7	Gelatin	BP	Gelling Agent
8	Glycerol	BP	Plasticizer
9	Liquid Sorbitol (Non Crystallizing)	BP	Plasticizer
10	Methyl Hydroxy benzoate	BP	Preservative
11	Propyl Hydroxy benzoate	BP	Preservative
12	Titanium dioxide	BP	Opacifier
13	Pantone colour shade 032 U	IHS	Colourant



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14	Purified water	IHS	Solvent
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Shelf life

24 Months

Special precautions for storage

Store below 30°C. Protect from light and moisture.

Nature and contents of container:

3X 10's blister pack

Marketing Authorization Holder:

Name: **GALAXY PHARMACEUTICALS,**

Address: Building No. 36, Gala No. 2, 3, 4A, Kopar, Purna, Bhiwandi, Thane - 421302, Mumbai (Maharashtra)

Country: INDIA

Telephone No: 022-49719061/022-49718955

Name and Address of Manufacturer:

Name: **SOFTGEL HEALTHCARE PRIVATE LIMITED,**

Address: Survey No.20/1, Vandalur- Kelambakkam Road, Pudupakkam Village, Kancheepuram District, Tamilnadu – 603 103, India