



GALAXY'S NEUROCARE
(Methylcobalamin, Gamma Linolenic Acid, Alpha Lipoic Acid, Folic acid, Pyridoxine hydrochloride, Biotin, Chromium, Zinc Capsules)

1.4.1 PRESCRIBING INFORMATION (SPC)

Proprietary Name

GALAXYS NEUROCARE CAPSULES

Approved Generic Name

Methylcobalamin, Gamma Linolenic Acid, Alpha Lipoic Acid, Folic acid, Pyridoxine hydrochloride, Biotin, Chromium, Zinc Capsules

Qualitative & Quantity formula:

Each soft gelatin capsule contains:

| | | |
|--|-----|---------|
| Methylcobalamin | | 1500mcg |
| Gamma Linolenic Acid (From Borage oil BP) | | 60mg |
| Alpha Lipoic Acid | USP | 100mg |
| Folic Acid | BP | 1.5mg |
| Pyridoxine Hydrochloride | BP | 3mg |
| Biotin | USP | 3mg |
| Elemental Chromium (as Chromium Picolinate USP) | | 100mcg |
| Elemental Zinc (as Zinc Sulfate USP) | | 10mg |
| Excipients | | q.s |



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Quantitative Declaration
Batch Size: 2, 50,000 capsules

| S. No | Ingredients | Label Claim | Over-ages (%) | Specific ation ¹ | Quantity Per capsule (mg/cap) | Quantity per capsule (kg/batch) | Function |
|------------------------------------|--|-------------|---------------|-----------------------------|-------------------------------|---------------------------------|------------------------|
| FILL MATERIALS | | | | | | | |
| 1 | Methylcobalamin | 1500mcg | 50 | IHS | 2.250 | 562.500 gm | Vitamin supplement |
| 2 | Gamma Linolenic acid (from Borage oil) | 60.00 | -- | IHS | 300.000 | 75.000 | Dietary supplement |
| 3 | Alpha Lipoic acid | 100.00 | 20 | USP | 120.00 | 30.000 | Antioxidant |
| 4 | Folic acid | 1.50 | 50 | BP | 2.250 | 0.563 | Vitamin supplement |
| 5 | Pyridoxine hydrochloride | 3.00mg | 10 | BP | 3.300 | 0.825 | Vitamin supplement |
| 6 | Biotin | 3.00 mg | 30 | USP | 3.900 | 975.000 gm | Vitamin supplement |
| 7 | Chromium (As Chromium Picolinate) | 100.00mcg | -- | USP | 0.8045 | 201.125 gm | Nutritional supplement |
| 8 | Zinc (As Zinc sulphate monohydrate) | 10.00 mg | -- | USP | 27.450 | 6.863 | Minerals |
| 9 | Calcium hydrogen Phosphate | -- | -- | BP | 79.846 | 19.963 | Calcium replenisher |
| 10 | Butylated Hydroxyanisole | -- | -- | BP | 0.100 | 25.000 gm | Preservative |
| 11 | Butylated Hydroxytoluene | -- | -- | BP | 0.100 | 25.000 gm | Preservative |
| 12 | Hydrogenated Vegetable Oil | -- | -- | BP | 25.000 | 6.250 | Diluent |
| 13 | White bees wax | -- | -- | BP | 10.000 | 2.500 | stabilizing agent |
| 14 | Lecithin | -- | -- | USP | 15.000 | 3.750 | Emulsifying agent |
| 15 | Refined soya oil | -- | -- | BP | 10.000 | 2.500 | Diluent |
| SHELL MATERIALS² | | | | | | | |
| 16 | Gelatin ³ | -- | -- | BP | 150.248 | 37.562 | Gelling Agent |
| 17 | Glycerol | -- | -- | BP | 54.128 | 13.532 | Plasticizer |
| 18 | Liquid Sorbitol (Non-crystallising) | -- | -- | BP | 18.063 | 4.515 | Artificial sweetener |
| 19 | Methyl Hydroxybenzoate | -- | -- | BP | 0.880 | 0.220 | Preservative |
| 20 | Propyl Hydroxybenzoate | -- | -- | BP | 0.088 | 0.022 | Preservative |
| 21 | Titanium dioxide | -- | -- | BP | 1.262 | 0.315 | Opacifier |



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| | | | | | | | |
|----|-------------------|----|----|----|--------|-------|-----------------|
| 22 | Sunset yellow FCF | -- | -- | IH | 0.325 | 0.081 | Colouring agent |
| 23 | Ponceau 4R FCF | -- | -- | IH | 0.006 | 0.001 | Colouring agent |
| 24 | Purified Water | -- | -- | BP | 25.000 | 6.25 | Vehicle |

Abbreviation:

BP: British Pharmacopoeia

USP: United States Pharmacopoeia

IH: In-House

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

Clinical Particulars:

Therapeutic indications:

Requested indication: GALAXY'S NEUROCARE capsules can be used in the treatment of the following conditions Peripheral neuropathy, Diabetic neuropathy, Drug induced neuropathy and Diabetic complications.

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

It should be used with caution in duodenal or peptic ulcer and recurrent gastritis. In case of severe renal insufficiency requiring dialysis the dose should be reduced. In case of skin rash and fever treatment should be stopped.

Pediatric Use:

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

General use:



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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**Mecobalamin**

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

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

Pyridoxine

Pyridoxine in doses of 5 mg or more daily may appreciably reverse the effects of levodopa (Drugdex Evaluation, Pyridoxine).

Pyridoxine should not be co administered with altretamine as it alters the results of altretamine (Drugdex Evaluation, Pyridoxine).

Metabolism of Phenobarbital and phenytoin is increased if co administered with Pyridoxine
Co administration of pyridoxine with amiodarone might increase the chances of sunburn, blistering, or rashes on areas of skin exposed to sunlight

Pregnancy and lactation**Mecobalamin**

Mecobalamin 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.

Chromium

Chromium is likely safe during pregnancy and breast-feeding when taken by mouth in amounts that are equal to or less than "adequate intake" (AI) levels. However women should not take chromium supplements during pregnancy or breast-feeding unless advised to do so by their 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 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****Mecobalamine**

Mecobalamin is an important co factor for the enzyme methionine synthase which recycles homocysteine to methionine. This conversion prevents the increased levels of homocysteine which is responsible for deleterious effects on the vascular system and increased oxidative stress in the neuronal tissue.

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. 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

or 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.

Chromium polynicotinate

Chromium potentiates insulin by enhancing receptor binding, thereby stabilizing blood glucose levels. Chromium has been found to decrease C reactive protein (a marker for inflammation) and increase insulin receptor number and binding

Pyridoxine HCl

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, phosphorylytic 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 phospholipid synthesis, as a co-factor in a variety of reactions involving side-chain cleavage, including cystathionine synthase and cystathionase

Pharmacokinetic Properties**Mecobalamine**

Evidence indicates methylcobalamin is utilized more efficiently than cyanocobalamin to increase levels of one of the coenzyme forms of vitamin B12. Experiments have demonstrated similar absorption of methylcobalamin following oral administration. The quantity of cobalamin detected

Following a small oral dose of methylcobalamin is similar to the amount following administration of cyanocobalamin; but significantly more cobalamin accumulates in liver tissue following administration of methylcobalamin. Human urinary excretion of methylcobalamin is about one third that of a similar dose of cyanocobalamin, indicating substantially greater tissue retention

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

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

Chromium polynicotinate

The exact mode of absorption and distribution of chromium polynicotinate in humans is unknown. However, as the nicotinate complex is partially broken down to its components, trivalent chromium and nicotinic acid in stomach acid, it is postulated that chromium and nicotinic acid are absorbed by the usual mechanisms, in addition to a component absorbed as the complex

Pyridoxine HCl

Pyridoxine and its vitamins 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 dephosphorylation, followed by metabolic trapping intracellularly as pyridoxine 5 phosphate

Pharmaceutical Particulars :

List of excipients

Calcium hydrogen Phosphate

Butylated Hydroxyanisole

Butylated Hydroxytoluene

Hydrogenated Vegetable Oil

White bees wax

Lecithin

Refined soya oil



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Gelatin3
Glycerol
Liquid Sorbitol (Non-crystallising)
Methyl Hydroxybenzoate
Propyl Hydroxybenzoate
Titanium dioxide
Sunset yellow FCF
Ponceau 4R FCF
Purified Water

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