SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)

1. NAME OF THE MEDICINAL PRODUCT:

Galaxy's NEUROCARE D

(Benfotiamine, Mecobalamin, Alpha Lipoic Acid, Inositol, Folic Acid, Chromium Polynicotinate& Pyridoxine Hydrochloride Capsules)

2. Qualitative and quantitative composition

Each soft gelatin capsule contains:

Benfotiamine		150 mg
Mecobalamin		1500 mcg
Alpha Lipoic Acid	USP	200 mg
Inositol	USP	100 mg
Folic Acid	BP	1.5 mg
Chromium Polynicotinate		200 mcg
Pyridoxine Hydrochloride	BP	3mg

Excipients: For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM:

Soft Gelatin Capsules

Maroon coloured oblong shaped opaque soft gelatin capsules containing yellowish brown colorued oily mass.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Galaxy Neurocare-D is indicated for Diabetic neuropathy, Peripheral neuropathy, Retinopathy

4.2 Posology and method of administration Dosage:

As directed by the Physician

Method of administration: Oral

4.3 Contraindications

Galaxy's Neurocare D is contraindicated if the user is known to be hypersensitivity to any of the ingredient in the formulation.

4.4 Special Warning & Precaution for use

Patients with diabetes taking hypoglyceamic 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.

4.5 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 altertamine (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

4.6 Pregnancy and lactation Benfotiamine
If you are pregnant, may become pregnant, breastfeeding, or are undergoing treatment for cancer, consult your health care professional before using this product

Mecobalamin
Mecobalamin is not recommended in pregnancy and lactation.

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

Inositol
If you become pregnant, contact your doctor. You will need to discuss the benefits and risks of using Inositol Niacinate while you are pregnant. It is not known if Inositol Niacinate is found in breast milk. If you are or will be breast-feeding while you use Inositol Niacinate,

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.

4.7 Effects on ability to drive and use machines
None reported.

4.8 Undesirable effects
Ingredients present in Neurocore D are generally well tolerated but mild side effects like nausea, headache etc. might be observed.
Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org.

4.9 OVERDOSE
No data available

5. PHARMACOLOGICALPROPERTIES:
5.1 Pharmacodynamic properties Benfotiamine
Benfotiamine increases transketolase activity, an important enzyme in glucose metabolism, and as a result, blocks three of the major molecular pathways leading to hyperglycemic damage in diabetic individuals thereby exhibiting positive effects in diabetic neuropathy and diabetic vascular complications. Benfotiamine corrects thiamine deficiency and can decrease the incidence of neuropathies

Mecobalamine
Mecoalamin 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 diabtic complications

Inositol
A change in CNS availability of inositol may produce altered brain signaling and eventually lead to the development of neurological disorders. Neuronal endoplasmic store of calcium can be accessed by stimulation by inositol. The inositol triphosphate released from the cell membrane travels through the cytoplasm until it reaches the enoplasmic reticulum. This inositol then releases the sequestered calcium, which can go on to mediate the release of neurotransmitters in response to depolarization. A change in CNS availability of inositol may produce altered brain signaling and eventually lead to the development of neurological disorders .Further, inositol acts as a second messenger to a number of rectors such as cholinergic, serotonergic, adrenergic, histaminergic etc. Most of these receptors are located in various organ systems. Theoretically, an imbalance of inositol concentration could potentially affect the development and function of one or all of these receptors

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 Mecobalamin. With the help of the enzyme methionine synthase, Mecobalamin 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, 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 phospholipid synthesis, as a co-factor in a variety of reactions involving side-chain cleavage, including cystathionine synthase and cystathionase

5.2 Pharmacokinetic Properties Benfotiamine

Vitamin B1 is associated with a 120-fold greater increase in the levels of metabolically active thiamine diphosphate. Unlike thiamine, benfotiamine's structure contains an open thiazole ring that closes once it is absorbed, producing biologically active thiamine. Its lipid solubility allows it to penetrate the nerves more readily. Benfotiamine is absorbed via passive diffusion through the intestinal mucosa and is rapidly converted to biologically active thiamine. Peak plasma concentrations of thiamine after oral benfotiamine administration are at least five times greater than those observed after oral administration of water-soluble thiamine salts. Half-life of benfotiamine is similar to thiamine salts, but bioavailability of benfotiamine eight days after administration is roughly 25 percent of the original dose

Mecobalamin

Evidence indicates Mecobalamin is utilized more efficiently than cyanocobalamin to increase levels of one of the coenzyme forms of vitamin B12. Experiments have demonstrated similar absorption of Mecobalamin following oral administration. The quantity of cobalamin detected following a small oral dose of Mecobalamin is similar to the amount following administration of cyanocobalamin; but significantly more cobalamin accumulates in liver tissue following administration of Mecobalamin. Human urinary excretion of Mecobalamin 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 intestitines 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

Inositol

Inositol phosphates are synthesized from the parent molecule inositol, with daily dietary consumption of inositol. Once inositol reaches the cells of the intestinal tract, it is phosphorylated to create inositol hexaphosphate, 5,6 and then subsequently dephosphorylated to its lower forms (IP1-5), which play important roles in signal transduction

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 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.

5.3 Pre-clinical safety data
Not applicable

6. PHARMACEUTICAL PARTICULARS:

6.1 List of Excipients

S.No	INGREDIENTS	SPECIFICATION
1.	Microcrystalline cellulose	BP
2.	Dicalcium phosphate anhydrous	BP
3.	Hydrogenated Vegetable Oil	BP
4.	White bees wax	BP
5.	Butylated Hydroxy Anisole	BP
6.	Butylated Hydroxy Toluene	BP
7.	Lecithin	USP
8.	Refined Soya Oil	BP
9.	Glycerol	BP
10.	Liquid Sorbitol (Non-Crystallising)	BP
11.	Sodium Methyl Hydroxybenzoate	BP
12.	Sodium Propyl Hydroxybenzoate	BP
13.	Purified water	BP
14.	Gelatin	BP
15.	Fumaric acid	USP
16.	Titanium dioxide	BP
17.	Ponceaue 4R	IH
18.	Indigo carmine	IH
19.	Brilliant blue	IH

20.	Sunset yellow	IH

6.2 Incompabilities
Not applicable

6.3 Shelf life
24 months

6.4 Special precautions for storage
Store below 30 ° C. Protect from direct sunlight. Keep medicines out of reach of children

6.5 Nature and contents of container
a) Type of package
Galaxy's Neurocore D is packed into 210mm PVC/PVDC White Opaque blister packs sealed with 200mm Aluminium Foil. The secondary packaging materials are a Carton and leaflet.

b) Nature and packaging material
3x10's Blister pack

6.6 Special Precautions for Disposal and Other Handling
Not applicable.

7. Marketing authorization holder and manufacturing site address
Manufacturing site address
Manufacturer:
SOFTGEL HEALTHCARE PVT LIMITED
Survey no. 20/1, vandalur- kelambakkam road, Pudupakkam village, Kancheepuram district– 603 103, Tamilnadu. India

Marketing authorization holder
Galaxy Pharmaceutical Ltd
PO Box 39107-00623, Nairobi, Kenya

8. Marketing Authorization Number
H2017/CTD2975/014

9. Date of first Registration / Renewal of the Registration-
16th March 2017

10. Date of Revision of the text–
20.01.2026