

Product information leaflet (For all products subject to medical prescription)**1. What NEUROCARE - 25 is and what it is used for?**

NEUROCARE - 25 is a combination of Methylcobalamin, Pregabalin, Folic Acid, Pyridoxine hydrochloride Alpha lipoic.

NEUROCARE - 25 is indicated for Peripheral Neuropathy, Diabetic Neuropathy, Drug induced Neuropathy, Fibromyalgia, Adjunctive therapy for adult patients with partial onset seizures.

2. What you need to know before you take NEUROCARE - 25**Warnings and Precautions**

It should not be used in patients on Levodopa therapy and hypersensitivity to any of the above ingredients.

Contraindications

NEUROCARE - 25 is contraindicated if the user is known to be hypersensitive to any of substances used in the formulation.

Interaction with other medicinal products and other forms of interaction

Absorption of methylcobalamin from the gastro-intestinal tract may be reduced by neomycin, aminosalicilyc acid, histamine H2-receptor antagonists and colchicine.

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

Fertility, pregnancy and lactation

May be or may not be harmful to an unborn baby. Consult a healthcare provider if you are in gestation or plan to have a baby during treatment.

It is not known whether it can pass through the breast milk or not. Nursing mothers should avoid breastfeeding while taking the capsule.

Effects on ability to drive and use machines

NEUROCARE - 25 may have minor or moderate influence on the ability to drive and use machines. NEUROCARE - 25 may cause dizziness and somnolence and therefore may influence the ability to drive or use machines. Patients are advised not to drive, operate complex machinery or engage in other potentially hazardous activities until it is known whether this medicinal product affects their ability to perform these activities.

Overdose

In case of overdose, treatment should include general supportive measures and may include haemodialysis.

3. How to take NEUROCARE - 25

Always take this medicine exactly as your doctor has told you.

Check with your doctor or pharmacist if you are not sure.

Your doctor will determine what dose is appropriate for you.

NEUROCARE - 25 is for oral use only.

4. Possible side effects:

Undesirable effects

Adverse effects reported are: nausea, headache, dizziness, somnolence, dry mouth, edema etc.

Tell your doctor if any of the side effects gets serious or lasts longer than a few days, or if you notice any side effects not listed in this leaflet

5. How to store NEUROCARE - 25?

Store below 30°C, protect from direct sunlight.

Keep medicines out of reach of children.

Do not use this medicine after the expiry date which is stated on the pack, after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

NEUROCARE 25

(Methylcobalamin, Pregabalin, Folic acid, Pyridoxine hydrochloride & Alpha Lipoic acid Capsules)

Composition:

Each soft gelatin capsule contains:

Methylcobalamin		750mcg
Pregabalin		25mg
Folic acid	BP	1.5mg
Pyridoxine hydrochloride	BP	3mg
Alpha Lipoic acid	USP	100mg

Therapeutic indications

Neurocare 25 is indicated for

Diabetic neuropathy

Peripheral neuropathy

Drug induced Neuropathy

Fibromyalgia

Dosage & administration

Dosage:

As directed by the Physician

Method of administration: Oral

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

Pregabalin

Pregabalin (S)-3-(aminomethyl)-5-methylhexanoic acid) is a structural derivative of the inhibitory neurotransmitter alpha-aminobutyric acid (GABA). It has anticonvulsant, analgesic and anxiolytic activity. Pregabalin is used in the management of neuropathic pain, peripheral neuropathy, fibromyalgia and used as an adjuvant therapy for adult patients with partial onset seizures

Special warning & precautions

Patients with diabetes taking hypoglycemic 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.

Contraindications:

Neurocare 25, is contraindicated if the user is known to be hypersensitivity to any of the ingredient in the formulation.

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.

Overdose

None reported.

Drug Interactions**Methylcobalamin**

Absorption of methylcobalamin from the gastro-intestinal tract may be reduced by neomycin, aminosalicyclic acid, histamine H2-receptor antagonists and colchicine.

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

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 Pyridoxine should not be co administered with altretamine as it alters the results of altretamine 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

Effects on ability to drive and use machines

None reported.

Adverse Reactions

Ingredients present in Neurocare 25 are generally well tolerated but mild side effects like nausea, headache etc might be observed.

Storage condition

Store below 30 ° C .Protect from direct sunlight

Keep medicines out of reach of children

Packaging Available

3x10's Blister pack

Trademark owned by**Manufactured by in India:**

Old Survey No. 20/1, new survey No. 9/810

Vandalur – Kelambakkam Road,

Pudupakkam Village, Kancheepuram District – 603 103, Tamilnadu, India