

# ReNerve<sup>®</sup> PLUS-BT

Softgel Capsules

## COMPOSITION:

Each soft gelatin capsule contains:

Methylcobalamine	1500	mcg
Alpha lipoic acid	100	mg
Inositol	100	mg
Folic acid	1.5	mg
Chromium Polynicotinate	200	mcg
Selenium dioxide	55	mcg
Benfotiamine	150	mg

Approved colours used in the capsule shell.

Appropriate overages of vitamins added to compensate for loss on storage.

## Clinical pharmacology

### Methylcobalamine

The chemical name for methylcobalamin is Coa-[ $\alpha$ -(5,6-dimethylbenz-1H-imidazolyl)]-Co $\beta$ -methylcobamide. The molecular formula is C<sub>63</sub>H<sub>91</sub>CoN<sub>13</sub>O<sub>14</sub>P and its molecular weight is 1344.4 g/mol. Methylcobalamin is one of the two forms of biologically active vitamin B<sub>12</sub>. It is the principle form of circulating vitamin B<sub>12</sub>, hence the form which is transported into peripheral tissue.

Methyl-B is absorbed by the intestine by a specific mechanism which uses the intrinsic factor and by a diffusion process in which approximately 1% of the ingested dose is absorbed. Cyanocobalamin and hydroxycobalamin are forms of the vitamin that require conversion to methylcobalamin

### Alpha-lipoic acid

Alpha-lipoic acid (LA), also known as thioctic acid, is a naturally occurring dithiol compound that functions as a cofactor for many mitochondrial enzymes involved in energy metabolism. Endogenous Alpha-lipoic acid is bound to proteins and is involved in acyl-group transfer reactions. Both in vivo and in vitro studies demonstrate that LA exhibits the ability to scavenge free radicals, chelate redox-active transition metals, regulate the detoxification of heavy metals, and modulate various signal transduction pathways in physiological and pathological conditions.

Alpha-lipoic acid can also be absorbed from the diet, and natural food sources, as well as from nutritional supplements.

### Inositol

Inositol which is a carbocyclic polyol that plays an important role as the structural basis for a number of secondary messengers in eukaryotic cells.

### Folic acid

In man, an exogenous source of folate is required for nucleoprotein synthesis and the maintenance or normal erythropoiesis. Folic acid is the precursor of tetrahydrofolic acid, which is involved as a cofactor for transformylation reactions in the biosynthesis of purines and thymidylates of nucleic acids. Impairment of thymidylates synthesis in patients with folic acid deficiency is thought to account for the defective deoxyribonucleic acid (DNA) synthesis that leads to megaloblast information and megaloblastic and macrocytic anemias.

### Chromium polynicotinate

Chromium is an essential trace mineral. Chromium functions as an organic complex known as glucose tolerance factor (GTF), which is thought to be a complex of chromium, nicotinic acid and amino acids. It potentiates the action of insulin and thus influences carbohydrate, fat and protein metabolism. Chromium also appears to influence nucleic acid synthesis and to play a role in gene expression.

### Selenium di oxide

Selenium is an essential trace element. Selenium functions as an integral part of the enzyme glutathione peroxidase and other selenoproteins. Glutathione peroxidase prevents the generation of oxygen free radicals that cause the destruction of polyunsaturated fatty acids in cell membranes. Selenium spares the requirement for vitamin E and vice versa. Selenium has additional effects, particularly in relation to the immune response and cancer prevention, which are not entirely due to these enzymic functions.

### Benfotiamine

Benfotiamine is a S-acyl derivative of thiamine with better bioavailability than thiamine. It prevents the development and the progression of diabetic complications. It was suggested that treatment with benfotiamine blocks three major pathways (the hexosamine pathway, the advanced glycation end product formation pathway and the diacylglycerol-protein kinase pathway) of hyperglycemic damage, probably by removal of glyceraldehydes 3-phosphate and fructose 6-phosphate through activation of the pentose phosphate enzyme transketolase.

Maximum plasma levels of thiamine are about 5-fold higher after benfotiamine intake and the bioavailability is at maximum about 3.6 times as high as that of thiamine hydrochloride and better than that of other lipophilic thiamine derivatives

## Indications and usage

**Renerve Plus BT** indicated for -

- Treatment of Diabetic neuropathy, Nephropathy and Retinopathy.
- Prevention of oxidative stress in high risk patient and occupational hazard.
- Maintenance in convalescence.

## Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients.

## Interactions

Folic acid may interact with 5-Fluorouracil, phenytoin, Capecitabine, Fosphenytoin, Methotrexate, Phenobarbital, Primidone and Pyrimethamine.

Before taking RENERVE PLUS BT consult your doctor or personal physician or healthcare provider if you are taking any prescription medicines or over the counter medicines or herbal products.

This document does not contain all possible interactions. Therefore, before using this product, tell your doctor or pharmacist of all the products you use.

## Warnings & precautions

Do not exceed the stated dose. Keep out of the reach of children.

Any individual who has a specific health problem or is taking medications must first seek advice from his or her personal physician or healthcare provider before starting RENERVE PLUS BT.

## Pregnancy and Lactation

Consult your personal physician or healthcare provider before starting RENERVE PLUS BT

## Adverse reactions

Side effects are uncommon with RENERVE PLUS BT therapy, but may include flushing, dizziness, headache, nausea, vomiting, syncope, paraesthesia, rash, oedema, and postural hypotension. Mild gastro-intestinal upsets are rare but may occur.

If you experience any unusual effects or discomfort after taking this medicine, contact your doctor promptly.

## Symptoms of overdose and antidote

No case of poisoning or overdosage with RENERVE PLUS BT has been reported. In an emergency, it is suggested that the stomach be emptied by gastric lavage and the patient be treated symptomatically.

## Dosage and administration

One capsule of RENERVE PLUS BT can be administered orally once daily or as recommended by the doctor or physician.

## Presentation

15 capsules packed in blister such 2 blisters packed in a carton.

## Storage condition:

Store in a cool, dry place. Protect from light. Keep all medicines away from reach of children.