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

NEPHROCAPS
(Multivitamin capsules)

COMPOSITION
Each hard gelatin capsules contains:
Vitamin C I.P. (coated)……. 150 mg
Niacinamide I.P…… 100 mg
Calcium Pantothenate I.P. …… 50 mg
Pyridoxine Hydrochloride I.P. …. 3 mg
Thiamine Mononitrate I.P. …… 10 mg
Riboflavine I.P. (Vitamin B2) ……10 mg
Folic Acid I.P. …… 1.5 mg
Biotin U.S.P. ……...100 mcg
Vitamin B12 I.P. …….15 mcg
Approved colours used in capsule shells.
Appropriate overages of vitamin added to compensate for loss on storage.

INDICATIONS
For various vitamins deficiency states

DOSAGE AND ADMINISTRATION
Take one capsule a day or as directed by physician, orally.

CONTRAINDICATIONS
The product is contraindicated in patients with known hypersensitivity to any of the ingredients.

WARNINGS AND PRECAUTION
Folic acid supplementation may obscure pernicious anemia, in that hematologic remission can occur while neurological manifestations progress.

UNDESIRABLE EFFECTS
Allergic sensitizations have been reported following oral administration of folic acid.

OVERDOSE

CLINICAL PHARMACOLOGY
PHARMACODYNAMIC PROPERTIES
The following account summarizes the pharmacological effects of the vitamins and minerals in Nephrocaps Capsules and describes the conditions caused by deficiency of these.

<u>Vitamin C (Ascorbic Acid)</u>
Vitamin C cannot be synthesised by man therefore a dietary source is necessary. It acts as a cofactor in numerous biological processes including the hydroxylation of proline to hydroxyproline. In deficiency, the formation of collagen is, therefore, impaired. Ascorbic acid is

important in the hydroxylation of dopamine to noradrenaline and in hydroxylations occurring in steroid synthesis in the adrenals. It is a reducing agent in tyrosine metabolism and by acting as an electron donor in the conversion of folic acid to tetrahydrofolic acid is indirectly involved in the synthesis of purine and thymine. Vitamin C is also necessary for the incorporation of iron into ferritin. Vitamin C increases the phagocytic function of leucocytes; it possesses anti-inflammatory activity and it promotes wound healing. Deficiency can produce scurvy. Features include swollen inflamed gums, petechial haemorrhages and subcutaneous bruising. The deficiency of collagen leads to development of thin watery ground substances in which blood vessels are insecurely fixed and readily ruptured. The supportive components of bone and cartilage are also deficient causing bones to fracture easily and teeth to become loose. Anaemia commonly occurs probably due to Vitamin C's role in iron metabolism.

Niacinamide (Nicotinamide)

The biochemical functions of nicotinamide as NAD and NADP (nicotinamide adenine dinucleotide phosphate) include the degradation and synthesis of fatty acids, carbohydrates and amino acids as well as hydrogen transfer. Deficiency produces pellagra and mental neurological changes.

Pantothenic Acid (Calcium Pantothenate)

Pantothenic acid is incorporated into co-enzyme A and is involved in metabolic pathways involving acetylation which includes detoxification of drug molecules and biosynthesis of cholesterol, steroid hormones, mucopolysaccharides and acetylcholine. CoA has an essential function in lipid metabolism.

Vitamin B6 (Pyridoxine)

Pyridoxine, once absorbed, is rapidly converted to the co-enzymes pyridoxal phosphate and pyridoxamine phosphate which play an essential role in protein metabolism. Convulsions and hypochromic anaemia have occurred in infants deficient in pyridoxine.

Vitamin B1 (Thiamine)

Thiamine (as the coenzyme, thiamine pyrophosphate) is associated with carbohydrate metabolism. Thiamine pyrophosphate also acts as a co-enzyme in the direct oxidative pathway of glucose metabolism. In thiamine deficiency, pyruvic and lactic acids accumulate in the tissues. The pyruvate ion is involved in the biosynthesis of acetylcholine via its conversion to acetyl co-enzyme A through a thiamine-dependent process. In thiamine deficiency, therefore, there are effects on the central nervous system due either to the effect on acetylcholine synthesis or to the lactate and pyruvate accumulation. Deficiency of thiamine results in fatigue, anorexia, gastro-intestinal disturbances, tachycardia, irritability and neurological symptoms. Gross deficiency of thiamine (and other Vitamin B group factors) leads to the condition beri-beri.

Vitamin B2 (Riboflavine)

Riboflavine is phosphorylated to flavine mononucleotide and flavine adenine dinucleotide which act as co-enzymes in the respiratory chain and in oxidative phosphorylation. Riboflavine deficiency presents with ocular symptoms, as well as lesions on the lips and at angles of the mouth.

Folic Acid
Folic acid is reduced in the body to tetrahydrofolate which is a co-enzyme for various metabolic processes, including the synthesis of purine and pyrimidine nucleotides and hence in the synthesis of DNA. It is also involved in some amino acid conversion and in the formation and utilisation of formate. Deficiency of folic acid leads to megaloblastic anaemia.

Biotin
Biotin is a co-enzyme for carboxylation during the metabolism of proteins and carbohydrates.

Vitamin B12 (Cyanocobalamin)
Vitamin B12 is present in the body mainly as methylcobalamin and as adenosylcobalamin and hydroxocobalamin. These act as co-enzymes in the trans methylation of homocysteine to methionine; in the isomerisation of methylmalonyl co-enzyme to succinyl co-enzyme and with folate in several metabolic pathways respectively. Deficiency of Vitamin B12 interferes with haemopoiesis and produces megaloblastic anaemia.

PHARMACOKINETIC PROPERTIES
The following account describes the absorption and fate of each of the active constituents of Nephrocaps Capsules.

Vitamin C (Ascorbic Acid)
Ascorbic acid is readily absorbed from the gastro-intestinal tract and is widely distributed in the body tissues. Ascorbic acid in excess of the body's needs is rapidly eliminated in the urine and this elimination is usually accompanied by a mild diuresis.

Niacinamide (Nicotinamide)
Nicotinic acid is absorbed from the gastro-intestinal tract, is widely distributed in the body tissues and has a short half-life.

Calcium Pantothenate (Pantothenic acid)
Pantothenic acid is readily absorbed from the gastro-intestinal tract and is widely distributed in the body tissues. About 70% of pantothenic acid is excreted unchanged in the urine and about 30% in the faeces.

Vitamin B6 (Pyridoxine)
Pyridoxine is absorbed from the gastro-intestinal tract and converted to the active pyridoxal phosphate which is bound to plasma proteins. It is excreted in the urine as 4-pyridoxic acid.

Vitamin B1 (Thiamine)
Thiamine is absorbed from the gastro-intestinal tract and is widely distributed to most body tissues. Amounts in excess of the body's requirements are not stored but excreted in the urine as unchanged thiamine or its metabolites.

Vitamin B2 (Riboflavine)
Riboflavine is absorbed from the gastro-intestinal tract and in the circulation is bound to plasma proteins. It is widely distributed. Little is stored and excess amounts are excreted in the urine. In

the body riboflavine is converted to flavine mononucleotide (FMN) and then to flavine adenine dinucleotide (FAD).

Folic Acid

Folic acid is absorbed mainly from the proximal part of the small intestine. Folate polyglutamates are considered to be deconjugated to monoglutamates during absorption. Folic acid rapidly appears in the blood where it is extensively bound to plasma proteins. Some folic acid is distributed in body tissues, some is excreted as folate in the urine and some is stored in the liver as folate.

Biotin

Following absorption, biotin is stored in the liver, kidney and pancreas.

Vitamin B12 (Cyanocobalamin)

Cyanocobalamin is absorbed from the gastro-intestinal tract and is extensively bound to specific plasma proteins. A study with labelled Vitamin B12 showed it was quickly taken up by the intestinal mucosa and held there for 2 - 3 hours. Peak concentrations in the blood and tissues did not occur until 8 - 12 hours after dosage with maximum concentrations in the liver within 24 hours. Cobalamins are stored in the liver, excreted in the bile and undergo enterohepatic recycling. Part of a dose is excreted in the urine, most of it in the first eight hours.

EXPIRY DATE:

Do not use later than the date of expiry.

STORAGE

Store protected from light and moisture at a temperature not exceeding 25° C.
Keep out of reach of children

PRESENTATION

Nephrocaps is available in strip of 15 capsules.

MARKETED BY

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