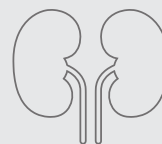


NephFit™

Amino Acid Ketoanalogues INN 600 mg



COMPOSITION

NephFit™ Tablet: Each film coated tablet contains-

- Calcium-3-methyl-2-oxo-valerate (α -ketoanalogue to isoleucine, calcium salt): 67 mg
- Calcium-4-methyl-2-oxo-valerate (α -ketoanalogue to leucine, calcium salt): 101 mg
- Calcium-2-oxo-3-phenylpropionate (α -ketoanalogue to phenylalanine, calcium salt): 68 mg
- Calcium-3-methyl-2-oxo-butyrate (α -ketoanalogue to valine calcium salt): 86 mg
- Calcium-DL-2-hydroxy-4-(methylthio) butyrate (α -hydroxyanalogue to methionine, calcium salt): 59 mg
- L-Lysine acetate USP : 105 mg (equivalent to L-Lysine 75 mg)
- L-Threonine USP: 53 mg
- L-Tryptophan USP: 23 mg
- L-Histidine USP: 38 mg
- L-Tyrosine USP: 30 mg

Total nitrogen content/tablet 36 mg.

Total Calcium content/tablet 1.25 mmol equivalent to Calcium/tablet 50 mg.

PHARMACOLOGY

This nutritional supplement contains amino acids, partly in form of their corresponding ketoanalogues, essential for patients with chronic kidney disease. It follows same catabolic pathways as amino acids and works by improving the metabolism of protein in the body, thereby improving the renal function. Amino Acid Ketoanalogues allows the intake of essential amino acids while minimizing the amino-nitrogen intake. The keto- and hydroxy-analogues are transaminated to the corresponding essential amino acids by taking nitrogen from non-essential amino acids, thereby decreasing the formation of urea by re-using the amino group, and causes absorption to occur.

INDICATION

NephFit™ is indicated for prevention and treatment of damages due to faulty or deficient protein metabolism in chronic kidney disease in connection with a limited dietary protein intake of 40 g/day or less (adult). Usually this applies to patients whose glomerular filtration rate (GFR) is less than 25 mL/min.

DOSAGE AND ADMINISTRATION

The recommended adult dose (70 kg body weight) of **NephFit™** is 4 to 8 tablets three times daily during meals. The tablets must not be chewed. Ingestion during meals facilitates proper absorption and the metabolization into the corresponding amino acids.

Paediatric population: No experience has been gained so far with the administration in paediatric patients.

SIDE EFFECTS

Hypercalcaemia (Very Rare). If hypercalcaemia occurs, the intake of vitamin D should be reduced. In case of persisting hypercalcaemia, the dose of it as well as the intake of any other calcium sources has to be reduced.

CONTRAINDICATION

- Hypersensitivity to the active substances or to any of the excipients
- Hypercalcaemia
- Disturbed amino acid metabolism

WARNING AND PRECAUTION

- The serum calcium level should be monitored regularly
- Ensure sufficient calorie intake
- In the presence of hereditary phenylketonuria, attention should be given to the fact that Amino Acid Keto Analogues contains phenylalanine
- Monitoring of the serum phosphate levels is needed in case of concomitant administration of aluminium hydroxide

DRUG INTERACTIONS

Concomitant administration of calcium-containing drugs may cause or aggravate elevated serum calcium levels. In case of aluminum hydroxide administration, the dose of NephFit™ has to be reduced if necessary.

Drugs that form hardly soluble compounds with calcium (e.g., tetracyclines, quinolones such as ciprofloxacin and norfloxacin as well as drugs containing iron, fluoride or estramustine) should not be taken at the same time with NephFit™ to avoid disturbed absorption of the active substance. An interval of at least two hours should elapse between the ingestion of these drugs.

The susceptibility to cardioactive glycosides, and hence the risk for arrhythmia will increase in Alpha ketoanalogue.

Monitoring of the serum phosphate levels is needed in case of concomitant administration of aluminum hydroxide.

USE IN PREGNANCY & LACTATION

There are no adequate data from the use of Amino Acid Keto Analogues in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/fetal development, parturition or postnatal development. Caution should be exercised when prescribing to pregnant women. No experience has been made so far with the use during lactation.

USE IN CHILDREN & ADOLESCENT

There are no adequate data from the use of Amino Acid Ketoanalogues in children & adolescent.

OVERDOSE

No case of overdose has been reported.

STORAGE

Store below 30°C. in a dry place, protect from light. Keep all medicine out of reach of children.

HOW SUPPLIED

NephFit™ Tablet: Each box contains 30 tablets in Alu-Alu Blister pack.

Manufactured by-



SQUARE
PHARMACEUTICALS PLC.
Bangladesh