

Alfacon

Amino Acid Keto Analogues

Presentation:

Alfacon Tablet: Each film-coated tablet contains Amino Acid Keto Analogues

Composition:

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- 105 mg, L-Threonine- 53 mg, L-Tryptophan- 23 mg, L-Histidine- 38 mg, L-Tyrosine- 30 mg, Total nitrogen content/tablet 36 mg, Calcium/tablet – 1.25 mmol \approx 50 mg

Mechanism of Action:

Amino Acid Keto Analogues tablets are administered for nutrition therapy in chronic kidney disease. Amino Acid Keto Analogues allows the intake of essential amino acids while minimising the amino-nitrogen intake.

Following absorption, 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. Hence, the accumulation of uraemic toxins is reduced. Keto and hydroxy acids do not induce hyperfiltration of the residual nephrons. Ketoacid containing supplements exert a positive effect on renal hyperphosphataemia and secondary hyperparathyroidism. Moreover, renal osteodystrophy may be improved. The use of Alfacon in combination with a very low protein diet allows to reduce nitrogen intake while preventing the deleterious consequences of inadequate dietary protein intake and malnutrition.

Indication:

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 & Administration:

Dosage:

Adults Dose: (70 kg body weight) is 4 to 8 tablets three times daily during meals. The tablets must not be chewed.

Ingestion during meals facilitates proper absorption and the metabolisation into the corresponding amino acids.

Method of administration: For oral use.

Duration of administration:

Amino Acid Keto Analogues tablets are administered as long as the glomerular filtration rate (GFR) is below 25 mL/min, and concomitantly, dietary protein is restricted to 40 gm/day or less (adult).

Contraindications:

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

Special warnings and precautions:

- 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 Interaction:

Concomitant administration of calcium-containing drugs may cause or aggravate elevated serum calcium levels.

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 Alfacon to avoid disturbed absorption of the active substances. An interval of at least two hours should elapse between the ingestion of Alfacon and these drugs.

Side effects:

Metabolism and nutrition disorders Very rare: hypercalcaemia

If hypercalcaemia occurs, the intake of vitamin D should be reduced. In case of persisting hypercalcaemia, the dose of Amino Acid Keto Analogues as well as the intake of any other calcium sources has to be reduced.

Use in specific population:

Pregnant Women:

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/foetal development, parturition or postnatal development. Caution should be exercised when prescribing to pregnant women.

Nursing Mother:

No experience has been made so far with the use during lactation

Children:

There is no experience in children.

Pharmaceutical Information:

Storage Condition:

Store in a cool (below 25^o C), dry place, away from light and moisture. Keep out of the reach of children.

Packaging:

Alfacon Tablet: Each box contains 6 x 10s Tablets in Alu-PVDC blister pack. Each blister supplied in sachet pack.

Manufactured by:

Beacon Pharmaceuticals PLC

Bhaluka, Mymensingh, Bangladesh

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