

PACKAGE INSERT

biocare
LIFESCIENCES INC

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

Ketoanalogues + Essential Amino Acids

AKLOG

Film-coated Tablet
Renal Nutritional Therapy



FORMULATION:

Each film-coated tablet contains:

Calcium-4-methyl-2-oxo-valerate.....	101 mg
Calcium-3-methyl-2-oxo-butyrate.....	86 mg
Calcium-2-oxo-3-phenylpropionate.....	68 mg
Calcium-3-methyl-2-oxo-valerate.....	67 mg
Calcium-DL-2-hydroxy-4-(methylthio) butyrate.....	59 mg
L-Lysine Acetate USP.....	105 mg
L-Threonine USP.....	53 mg
L-Histidine Free Base USP.....	38 mg
L-Tyrosine USP.....	30 mg
L-Tryptophan USP.....	23 mg

Total nitrogen content per tablet: 36 mg.

Calcium content per tablet: 1.25 mmol = 50 mg

DESCRIPTION

Each tablet contains calcium-3-methyl-2-oxovalerate (α -ketoanalogue to isoleucine, calcium salt) 67 mg, calcium-4-methyl-2-oxovalerate (α -ketoanalogue to leucine, calcium salt) 101 mg, calcium-2-oxo-3-phenylpropionic acid (α -ketoanalogue to phenylalanine, calcium salt) 68 mg, calcium-3-methyl-2-oxobutyrate (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 equivalent to L-lysine 75 mg, L-threonine 53 mg, L-tryptophan 23 mg, L-histidine 38 mg, L-tyrosine 30 mg.

Total nitrogen content/tablet: 36 mg.

Calcium content/tablet: 1.25 mmol=50 mg

Pharmacology:

Pharmacodynamics: AKLOG 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 positive effect on renal hyper phosphataemia and secondary hyperparathyroidism. Moreover, renal osteodystrophy may be improved. The use of AKLOG in combination with a very low protein diet allows to reduce nitrogen intake

PHARMACOKINETICS:

In normal individuals, there is an increase in the plasma level of ketoanalogues, 10 minutes after oral ingestion. These levels reach values that are approximately 5 times higher than the initial level. Peak levels are reached within 20-60 min, and normal levels are reached again after 90 min. Gastrointestinal absorption is thus very rapid. In the plasma, a simultaneous increase in levels of the ketoanalogue and the corresponding amino acid show that transamination of the ketoanalogue is very rapid. Due to the natural pathways of disposal of α -ketonic acids in the organism, it is probable that exogenous intakes are very rapidly integrated into metabolic cycles. Ketoacids follow the same catabolic pathways as the classical amino acids.

THERAPEUTIC ACTION:

Normalizes metabolic process, promotes recycling product exchange. Reduces ion concentration of potassium, magnesium and phosphate.

INDICATIONS/ USES

Prevention and therapy of damages due to faulty or deficient protein metabolism in chronic renal insufficiency in connection with limited protein in food of 40 g/day (for adults) ie, generally in patients with a glomerular filtration rate (GFR) between 5 and about 15 ml/minutes.

DOSAGE/DIRECTION FOR USE

For oral use.

Adults (70 kg body weight): If not otherwise prescribed, take 4 to 8 tablets three times a day during meals. Swallow whole.

Duration of Application: AKLOG tablets are given as long as the glomerular filtration rate (GFR) is between 5 and about 15 mL/minute. Simultaneously food should contain 40 g/day protein or less (adults).

CONTRAINDICATIONS:

- Allergy and hypersensitivity to any content of this drug
- Hypercalcemia
- Disturbed amino acid metabolism
- Caution use for patients with phenylketonuria

Warning:

Ketoanalogues + Essential amino acids AKLOG contains phenylalanine, it should be used with caution in phenylketonuric patients.

SPECIAL PRECAUTIONS

In the presence of hereditary phenylketonuria, attention should be given to the fact that AKLOG contains phenylalanine.

PREGNANCY & LACTATION:

No experience has been made so far with the administration of Ketoanalogues + Essential amino acids AKLOG as well as any source of calcium.

SIDE EFFECTS

Hypercalcemia may develop. In this case it is recommended to decrease Vitamin D intake. If hypercalcaemia persists, reduce the dosage of AKLOG as well as other source of calcium.

The serum calcium level should be monitored regularly.

Ensure sufficient calorie intake.

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

DRUG INTERACTIONS

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

Uraemic symptoms improve under therapy with AKLOG. Thus, in case of aluminium hydroxide administration, the dose of this drug has to be reduced if necessary. Serum phosphate levels should be monitored for a decrease. Drugs that form sparingly 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 AKLOG to avoid disturbed absorption of the active substance. An interval of at least two hours should elapse between the ingestion of AKLOG and these drugs.

The susceptibility to cardioactive glycosides, and hence the risk for arrhythmia will increase in AKLOG produces elevated serum calcium levels).

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

AVAILABILITY:

Alu-Alu Blister pack of 10's, box of 100 film-coated tablets.

STORAGE:

Store at temperatures not exceeding 30°C. Protect from light.

CAUTION:

Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

ADR STATEMENT:

For suspected adverse drug reaction/s, report to the **FDA**: www.fda.gov.ph and to **Biocare Lifesciences, Inc**: pv@biocarelifesciences.com

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