SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Ketogress (Alpha Ketoanalogue Tablets)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains;
Calcium-3 methyl-2-oxo-valerate 67 mg
Calcium-4-methyl-2-oxo-valerate 101 mg
Calcium-2-oxo-3-Phenylpropionate 68 mg
Calcium-3-methyl-2-oxo-butyrate 86 mg
Calcium-DL-2-hydroxy-4-(methylthio)-butyrate 59 mg
Lysine Acetate USP
Eq to L-Lysine 75 mg
L-Threonine USP 53 mg
L-Tryptophan USP 23 mg
Histidine 38 mg
L-Tyrosine USP 30 mg
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film Coated Tablet.
Pearl yellow, capsule shaped biconvex, film coated tablets debossed with "LA RENON" on one side and plain on other side.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Prevention & therapy of damages due to deficient or faulty protein metabolism in chronic renal insufficiency due to a protein deficient (≤40 g/day) diet (for adults).

a) Reduction of uremic symptom

b) Prevent degradation of body protein
c) Reduction of proteinuria

d) Decreased secondary hyperparathyroidism and renal osteodystrophy

e) Normalization of carbohydrate metabolism
f) Improvement of the disturbed serum lipid profile

g) Improvement of endocrine disturbances

h) Increases the intervals between two dialysis

4.2 Posology and method of administration

For oral use. The dose of Ketogress is 1tab/5kg body wt. /day. A person weighing 60 kg will require 12 tabs/day.

Ketogress is given as long as the GFR is <25 mL/min and a diet with an intake of maximum 40 g protein/day (for adults) is followed.

Should be taken with food. Swallow whole, do not chew/crush.

4.3 Contraindications

Hypercalcaemia, disturbed amino acid metabolism. In case of hereditary phenylketonuria, it has to be taken into account that Ketogress contains phenylalanine.

4.4 Special warnings and precautions for use

Ketogress should be taken during meals to allow proper absorption and metabolism into the corresponding amino acids. The serum calcium level should be monitored regularly. Ensure the sufficient supply with calories.

4.5 Interaction with other medicinal products and other forms of interaction

The simultaneous administration of medicaments containing calcium (eg, acetolyte) may lead to pathological increases of the serum calcium level or intensification.

In order not to interfere with absorption, do not take drugs together with Ketogress that form sparingly soluble compounds with calcium (eg, tetracyclines, quinolone eg, ciprofloxacin and norfloxacin, iron-, fluoride- and estramustin-containing drugs). Between the intake of Ketogress and drugs from the mentioned categories, a period of at least 2 hrs should pass.

4.6 Fertility, pregnancy and lactation

Use in pregnancy & lactation: No experience has been made so far with the application in pregnancy and lactation.

4.7 Effects on ability to drive and use machines

Ketogress has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Hypercalcaemia may develop. In this case, it is recommended to decrease vitamin D intake. If the hypercalcaemia persists, reduce the dosage of Ketogress as well as any other source of calcium.

4.9 Overdose

No symptoms have been observed to date.

5 PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Not applicable

ATC code: Not applicable

5.1 Pharmacodynamic properties

KETOGRESS allows the intake of essential amino acids while minimizing the amino-nitrogen intake. Following ingestion, the keto analogues are transaminated by taking nitrogen from non-essential amino acids, thereby decreasing the formation of urea by re-using the amino group. The levels of accumulating uremic toxins are decreased. Keto-and/or hydroxy-acids do not elicit hyperfiltration of residual nephrons. Ketoacid-containing supplements have a positive infuence on the renal hyperphosphatemia and secondary hyperparathyroidism and can improve renal osteodystrophy. The use of Ketogress in association with a very low protein diet allows a reduced intake of nitrogen while avoiding the deleterious consequences of inadequate dietary protein intake and malnourishment.

5.2 Pharmacokinetic properties

The plasma kinetics of amino acids and their integration in metabolic pathways are well established. In uremic patients, the plasma disturbances do not seem to depend on digested amino acid intake, and that the post-absorptive kinetics seems to be disturbed very early in the development of the disease. In normal individuals, there is an increase in the plasma level of keto-analogues, 10 min 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 keto-analogue and the corresponding amino acid show that transamination of the keto-analogues 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.

5.3 Preclinical safety data

Preclinical data reveal no special hazards for humans based on conventional studies on pharmacological safety, acute and repeated dose toxicity, reproduction toxicity, and genotoxicity. The product does not show teratogenic properties.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Benzoate
Polacrilin potassium
Microcrystalline cellulose
Colloidal Silicon Dioxide
Sodium Bicarbonate
Povidone [Povidone K 30]
Isopropyl Alcohol
Colloidal Silicon Dioxide
Shellac (white)
Flavor Pineapple Dry
Sodium Starch Glycolate
Citric Acid Anhydrous
Magnesium Stearate
Insta Moist Shield [A21E00024]
Ferric Oxide (Yellow)
Hypromellose -15 cps
Polyethylene glycol-6000
Purified Talc
Titanium Dioxide
Ferric Oxide (Black)
Ferric Oxide (Yellow)
Flavor Pineapple Dry
Wincoat WT PRL 0025

6.2 Incompatibilities

None stated.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Do not store above 30°C. Protect from light & Moisture.

6.5 Nature and contents of container

Alu -Alu blister pack

10 tablets in a blister, 10 such blisters are packed in a primary carton along with the package insert.

10 tablets in a blister, 3 such blisters are packed in a primary carton along with the package insert.

6.6 Special precautions for disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

La Renon Healthcare Pvt. Ltd

207-208, ISCON Elegance, Circle-P,
Prahlad Nagar Cross Roads, S.G.

Highway, Ahmedabad-380015,
Gujarat, India
Manufactured at:
Stanford Laboratories Pvt. Ltd.
(A subsidiary company of La Renon Healthcare Pvt. Ltd)
8, Industrial Area, Mehatpur, Dist. Una, (H.P.) 174315,
India.

8 MARKETING AUTHORISATION NUMBER(S)

H2019/CTD6180/923ER

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorization: 17th August 2018

10 DATE OF REVISION OF THE TEXT

30th March 2026