



1. DRUG NAME
Aminorenocare®
2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Calcium -3-Methyl-2-oxo-Valerate	67mg
Calcium -4-methyl-2-oxo-valerate	101mg
Calcium-2-oxo-3-Phenylpropionate	68 mg
Calcium-3-methy-2-oxo-butyrate	86 mg
Calcium-DL-2-hydroxy-4(methylthio) butyrate	59 mg
L-Lysine monoacetate 105 mg Eq. to	75 mg
L-Lysine	
L-threonine	53 mg
L-Tryptophan	23 mg
L-Histidine	38 mg
L-Tyrosine	30 mg

See Paragraph 6.1 for the full list of excipients

3. PHARMACEUTICAL FORM

Film Coated tablet

4. CLINICAL DATA

4.1 Therapeutic indications:

In association with a strict low-protein diet (0.4 g/kg/day) in chronic renal failure patients (to mitigate the uremic syndrome and better control phosphorus/calcium metabolism)

4.2 Dosage and route of administration:

• **Dosage:**

1 tablet / 5 kg body weight
Maximum dose: 50 tablets/day

Pediatric patients:

No data available

Route of administration:

- Oral route
- Tablets are taken with the three meals (total daily dosage spread over the 3 meals of the day)
- Tablets should be swallowed whole without chewing

4.3 Contraindications:

- Hypersensitivity to the active substance(s) or to any of the excipients listed in Paragraph 6.1.
- Hypercalcemia

4.4 Special precautions and warnings:

A strictly poor protein diet (0.4 mg protein/kg/day) should be maintained throughout the duration of treatment.

Precautions during administration:

Low protein diet is accompanied by a considerable reduction in energy and is hypocaloric. Consequently, diet should be adjusted to provide an increased caloric intake (equal or higher than 35 kCal/kg/day).

Serum calcium should be carefully monitored for hazards of hypercalcemia (see Unwanted effects).

4.5 Interaction with other drugs and other forms of interaction:

Drug interactions requiring special precautions:

- Tetracyclines: Interference with tetracycline absorption is increased by the presence of calcium salts. A time lapse of 3 hours minimum is required between intake of either agent.

4.6 Fertility, pregnancy and breast-feeding:

This drug should be avoided in pregnant and breast-feeding women since no data is available.

4.7 Effects on driving and use of machines:

Not applicable

4.8 Unwanted effects:

- Rare digestive disturbances, commonly manifesting as epigastric heaviness
- Risk of hypercalcemia (which reverts to normal upon stopping treatment). Vitamin D supplementation is recommended in incidents of hypercalcemia. Dosage of Aminorenocare / other calcium containing drugs should be reduced.

4.9 Overdosage:

No reports of overdosage have been reported to date.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties:

Pharmacotherapeutic class: Gastrointestinal tract and metabolism drug (A: GASTROINTESTINAL TRACT AND METABOLISM)

Aminorenocare contains 5 essential amino acids (L-lysine monoacetate, L-threonine, L-tryptophan, L-histidine and L-tyrosine) and 5 essential amino acid substitutes in the form of calcium salts, including 4 keto-analogues (keto-isoleucine, keto-leucine, keto-valine and keto-phenylalanine) and a hydroxy-analogue (hydromethionine) as calcium salt. Keto-analogues convert to the corresponding amino acid by transamination by the action of an endogenous amine function. Addition of keto-analogues to a hypo-proteinic diet in chronic renal failure reduces protein malnutrition and deficiency of essential amino acids without nitrogen load.

5.2 Pharmacokinetic properties:

Not applicable

5.3 Preclinical safety data:

Not applicable

6. PHAMACEUTICAL DATA

6.1 List of excipients:

Avicel PH 112, Povidone K30, Talc purified, Sodium stearyl fumarate, Croscarmellose Sodium, Crosspovidone XL, Aerosil 200, Magnesium stearate, Polyethylene glycol 6000.

Film Coat: Eudragit E100, Talc purified, Polyethylene glycol 6000, Quinoline yellow Aluminium Lake E104, Triacetin, Titanium dioxide, Alcohol 96% (evaporates during processing)

6.2 Incompatibilities:

Not applicable

6.3 Shelf life

2 years

6.4 Special storage precautions:

Not applicable

6.5 Packaging nature and content:

Carton Box contains 10 strips of transparent AL/PVC/PVDC each of 10 tablets and each 5 strips enclosed in AL Pouch each two pouches inserted in carton box with a pamphlet

6.6 Special precautions for storage

Store at temperature not exceeding 30°C, In dry place.

Keep all medicaments out of reach of children



Product of:
AMOUN PHARMACEUTICAL Co.
S.A.E.
El-Obour City, Al Qalyubia, Egypt.

