

Neframin^{Tablet}

Alpha Ketoanalogues + Essential Amino acids

COMPOSITION: Each film coated Tablet contains:
α-keto analogue to isoleucine (calcium salt).....67mg
α-keto analogue to leucine (calcium salt)101mg
α-keto analogue to phenylalanine (calcium salt)68mg
α-keto analogue to valine (calcium salt).....86mg
α-keto analogue to methionine (calcium salt)59mg
L-lysine acetate.....105mg
L-threonine.....53mg
L-tryptophan.....23mg
L-histidine.....38mg
L-tyrosine.....30mg
Total nitrogen content.....36mg
Calcium.....0.05g

(Innovator's Specification)

INDICATIONS:

NEFRAMIN is prescribed for adults and children over 3 years of age. Indications for use are protein-energy deficiency, prevention and treatment of disorders that develop as a result of altered protein metabolism in chronic renal failure and in the case of insufficient intake of protein in the body with food.

DOSAGE & ADMINISTRATION:

The drug should be taken orally during meals, swallowing tablets whole, not chewing and not breaking.

The daily dose is divided into 3 divided doses. It is calculated in accordance with the weight of the patient - at the rate of 1 tablet for every 5 kg of body weight or 100 mg / kg. Adults with a weight of 70 kg prescribed for 4-8 tablets 3 times a day.

Take NEFRAMIN follows the entire period until the glomerular filtration rate reaches 25 ml / minute.

During the use of the drug must take into account the protein content in food. In the period before dialysis, its quantity should not exceed 40 g per day (a more accurate volume is determined depending on the degree of chronic renal failure). In the period of dialysis, the rate of protein intake is determined by the doctor.

Recommended daily protein content in food for children:

- From 3 to 10 years - 1.4-0.8 g / kg;
- Older than 10 years - 1-0.6 g / kg.

PHARMACOKINETICS:

The plasma kinetics of amino acids and their integration in metabolic pathways are well established. It should nevertheless be noted that in uremic patients, the cause of the changed plasma levels which occur frequently in these patients, does not seem to be the absorption of the supplied amino acids (i.e., the absorption itself is not disturbed). The changed plasma levels seem to be due to impaired post-absorptive kinetics, which can be detected in a very early stage of the disease. In healthy individuals, the plasma levels of ketoacids increase within 10 min after oral administration. Increases of up to 5-fold the baseline levels are achieved. Peak levels occur within 20-60 min and after 90 min, levels stabilize in the range of the base levels. Gastrointestinal absorption is thus very rapid. The simultaneous increase in levels of the ketoacids and the corresponding amino acids show that the ketoacids are transaminated very rapidly. Due to the physiological utilisation pathways of ketoacids in the body, it is likely that exogenously supplied ketoacids are very rapidly integrated into metabolic cycles. Ketoacids follow the same catabolic pathways as the classical amino acids. No specific study on ketoacid excretion has been performed to date.

SIDE-EFFECTS:

Hypercalcemia may develop if it occurs, Vitamin-D intake should be reduced.

Monitor regularly the serum calcium level.

The dose of NEFRAMIN and intake of other calcium sources has to be reduced. As the uremic symptoms improve under

نیفرامین ٹیبلٹ
(الفائیوٹاٹو ایسٹینیل + امینو ایسڈ)

Neframin, a possible administration of aluminium hydroxide should be reduced. Pay attention to a reduction of serum phosphate. In order not to interfere with absorption, do not take drugs together with the compounds that form sparingly soluble—compounds with calcium. e.g Tetracyclines, Ciprofloxacin and Norfloxacin, Iron-Fluride and Estramustine-containing drugs). An interval of at least 2 Hours should be observed Between the intake of Neframin-Tablets and drugs from the mentioned categories a period of at least 2 hours should pass. If the blood calcium concentration raises by the intake of NEFRAMIN the susceptibility towards certain drugs enhancing the heart strength (heart/cardiac-active glycosides) will increase and the risk of heart rhythm disturbance will increase.

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 NEFRAMIN contains phenylalanine. Monitoring of 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 NEFRAMIN 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. No experience has been made so far with the use during lactation. Use in children: No experience has been made so far with the administration in pediatric patients.

DRUG INTERACTIONS:

Concomitant administration of calcium-containing drugs may cause or aggravate elevated serum calcium levels. Drugs that form hardly soluble compounds with calcium (e.g., tetracycline, quinolones, e.g., ciprofloxacin and norfloxacin, drugs containing iron, fluoride or estramustine) should not be taken at the same time with NEFRAMIN to avoid disturbed absorption of the active substances. An interval of at least 2hrs. should elapse between the ingestion of NEFRAMIN and these drugs. The susceptibility to cardio active glycosides and hence, the risk for arrhythmia will increase if NEFRAMIN produces elevated serum calcium levels Uremic symptoms improve under therapy with NEFRAMIN. Thus, in case of aluminum hydroxide administration, the dose of NEFRAMIN has to be reduced, if necessary. Serum phosphate levels should be monitored for a decrease.

CONTRAINDICATIONS:

- Hypersensitivity to amino acids or to any of the excipients of NEFRAMIN.
- Hypercalcemia disturbed amino acid metabolism.

STORAGE & INSTRUCTIONS:

Store between 15-25°C.

Protect from heat, sunlight and moisture.

Keep away from the reach of children.

To be sold on prescription of registered medical practitioner only.

HOW SUPPLIED:
NEFRAMIN Tablet
100's Tablets.

خوراک و طبیعت استعمال:

ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات:

دوا کو ۱۵-۲۵ ڈگری سینٹی گریڈ درجہ حرارت کے درمیان رکھیں۔

دھوپ، گرمی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔

صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔

Manufactured by:

PHARMASOL
PRIVATE LIMITED
Plot # 549, Sundar Industrial Estate,
Lahore-Pakistan.