

COMPOSITION

Renocal Plus Tablet: Each film-coated tablet contains Calcium Acetate BP 435 mg equivalent to 110 mg Calcium and Heavy Magnesium Carbonate BP 235 mg equivalent to 60 mg Magnesium.

PHARMACOLOGY

As Calcium Acetate and Magnesium Carbonate are phosphate-binding compounds, they lead together with the phosphate contained in food to the formation of low solubility Calcium and Magnesium phosphate-salts in the gut, which then will be excreted with the faeces. Calcium Acetate reaches its maximal phosphate-binding capacity at a pH of 6–8. Therefore, Renocal Plus is also suitable for phosphate binding in patients with hypo or anacidity of the stomach.

INDICATION

Treatment of hyperphosphatemia associated with chronic renal insufficiency in patients undergoing dialysis (haemodialysis, peritoneal dialysis). Renocal Plus is indicated in adults.

DOSAGE & ADMINISTRATION

Adults: 3 to 10 film-coated tablets per day, depending on the serum phosphate level. The daily dose should be subdivided according to the number of meals per the day (usually 3 times a day). The recommended starting dose is 3 film coated tablets daily. If necessary, the dosage may be raised to maximally 12 film-coated tablets per day.

Paediatric population: The safety and efficacy of Renocal Plus in children and adolescence have not been established. Therefore, the administration of Renocal Plus is not recommended in children and adolescents below 18 years of age.

METHOD OF ADMINISTRATION

To achieve the maximum phosphate binding effect, Renocal Plus must be taken together with the meal and should not be crushed or chewed. For easy swallowing, the tablets should be taken together with some liquid. In case the tablets are too large to be swallowed by the patient, the tablets should be broken along the score line immediately before swallowing in order to avoid the development of taste of acetic acid. Renocal Plus can be applied long-term.

CONTRAINDICATIONS

Renocal Plus is contraindicated in patients with:

- Hypophosphataemia
- Hypercalcaemia with or without clinical symptoms, e.g. as a result of an overdose of vitamin D, a paraneoplastic syndrome (bronchial carcinoma, breast cancer, renal cell carcinoma, plasmacytoma), bone metastases, sarcoidosis or immobilisation osteoporosis;
- Elevated serum magnesium levels of more than 2 mmol/l, and/or symptoms of hypermagnesaemia;
- AV-block III°;
- Myasthenia gravis;

WARNINGS AND PRECAUTIONS

Renocal Plus should only be administered with caution (only with continuous monitoring of serum calcium, magnesium and phosphate) in case of severe hyperphosphataemia with a calcium-phosphate-product of more than 5.3 mmol/L if

- refractory to therapy
- refractory hyperkalaemia,
- clinical relevant bradycardia or AV-block II° with bradycardia.

Continuous monitoring of serum phosphate, serum magnesium, serum calcium and the calcium-phosphate-product should be performed, especially in case of simultaneous intake of vitamin D preparations and thiazide diuretics.

High doses and long-term administration of Renocal Plus may result in hypermagnesaemia. Hypermagnesaemia is mostly asymptomatic, but in some cases systemic effects may be seen.

Caution should be taken while taking antacids and digitalis glycosides.

If patients with a chronic renal insufficiency receive Renocal Plus they may develop hypercalcaemic episodes, especially in combination with the administration of metabolites of vitamin D.

Attention must be paid to the progression or the appearance of vascular and soft tissue calcifications. The risk decreases by lowering the calcium-phosphate-product to <4.5 mmol/L.

Increased intake of calcium salts may result in the precipitation of fatty acids and bile acid as calcium soap. This may lead to constipation. In case of diarrhoea the dosage of Renocal Plus should be reduced.

SIDE EFFECTS

Gastrointestinal disorders:

Common: Soft stools, gastrointestinal irritation like nausea, anorexia, sensation of fullness, belching and constipation, diarrhoea.

Metabolism and nutrition disorders:

Common: Hypercalcaemia either asymptomatic or symptomatic, asymptomatic hypermagnesaemia.

Uncommon: Moderate to severe symptomatic hypercalcaemia, symptomatic hypermagnesaemia.

Very rare: Hyperkalaemia, magnesium-induced osteal mineralisation disturbances.

USE IN PREGNANCY AND LACTATION

Pregnancy: There are no or limited amount of data from the use of Renocal Plus in pregnant women. Animal studies are insufficient with respect to reproductive toxicity. Renocal Plus should not be used during pregnancy unless the clinical condition of the woman requires treatment with Calcium Acetate and Magnesium Carbonate.

Breastfeeding: Calcium Acetate and Magnesium Carbonate are excreted in human milk to such an extent that effects on the breastfed newborns/infants are likely.

Breast-feeding is not recommended during treatment with Renocal Plus.

USE IN PAEDIATRIC POPULATION

The safety and efficacy of Renocal Plus in children and adolescence have not been established. Therefore, the administration of Renocal Plus is not recommended in children and adolescents below 18 years of age.

DRUG INTERACTIONS

To avoid any possible drug interaction between Renocal Plus and susceptible oral medication when taken concomitantly should be taken within the period 2 hours before and 3 hours after administration of Renocal Plus.

Renocal Plus affects the absorption of tetracyclines, doxycycline, norfloxacin, some cephalosporins like cefpodoxime, cefuroxime, and some quinolones (gyrase inhibitors) like ciprofloxacin, biphosphonates, fluorides, ketokonazole, estramustin-preparation, anticholinergics, iron supplements, digoxin, nitrofurantoin, levothyroxine. Vitamin D and derivatives, thiazide diuretics, oestrogens may affect the absorption of calcium.

The sensitivity for glycosides and therefore the risk for arrhythmia is increased by elevated serum calcium levels.

The administration of adrenalin in patients with increased serum Calcium levels may lead to severe arrhythmia.

The effect of Calcium antagonists may be reduced.

OVERDOSE

An acute hypermagnesaemia (either asymptomatic or with acute systemic toxicity) suppresses both the central and the peripheral neural activity by inhibiting acetylcholine release. Systemic toxicity, severe neurotoxic side effects, gastrointestinal disturbances, cystospasm, muscle weakness, lethargy, missing deep-tendon reflexes and disturbed AV-conduction and ventricular stimulus, arterial hypotension induced by vasodilatation, paralytic ileus, flaccid paralysis and coma have been observed with different serum concentrations. At a level of more than 10 mmol/l respiratory arrest and cardiac arrest occur.

Symptoms of hypercalcaemia are initially muscle weakness and gastrointestinal disturbances. Severe hypercalcaemia is characterised by disturbances of consciousness. In patients with a serum calcium level of more than 3.5 mmol/l a hypercalcaemic crisis is possible with the symptoms of polyuria, polydipsia, nausea, anorexia, constipation, pancreatitis (infrequent), arrhythmia, shortening of the QT-interval, adynamia, hypertension, muscle weakness up to pseudo paralysis, psychosis, somnolence up to coma. Long-term overdosing may lead to the development of an adynamic osteopathy.

EMERGENCY TREATMENT

In addition to symptomatic treatment, the therapy of hypermagnesaemia consists in lowering the magnesium-concentration of the dialysate and in a reduction of the dose of Renocal Plus.

During the treatment of hypercalcaemia with a calcium-free dialysate close monitoring of serum calcium concentration is necessary in order to minimise the risk of hypocalcaemia and adverse cardiovascular reactions.

STORAGE

To be dispensed only on the prescription of a registered physician. Store below 30°C, in a cool and dry place. Keep away from light. Keep out of the reach of children.

HOW SUPPLIED

Renocal Plus Tablet: Each box contains 3x10 tablets in Alu-PVC blister pack.

Manufactured by

Everest Pharmaceuticals Ltd.

BSCIC I/A, Kanchpur, Narayanganj, Bangladesh

