

A close-up photograph showing a hand wearing a pink nitrile glove filling small, round aluminum foil cups with a dark brown, granular powder. The cups are arranged in rows on a light-colored surface. The background is softly blurred, showing more of the workspace.

Fulfill ^{the}
purpose

Laretol

Calcitriol SGC 0.25 mcg

Laretol Injection

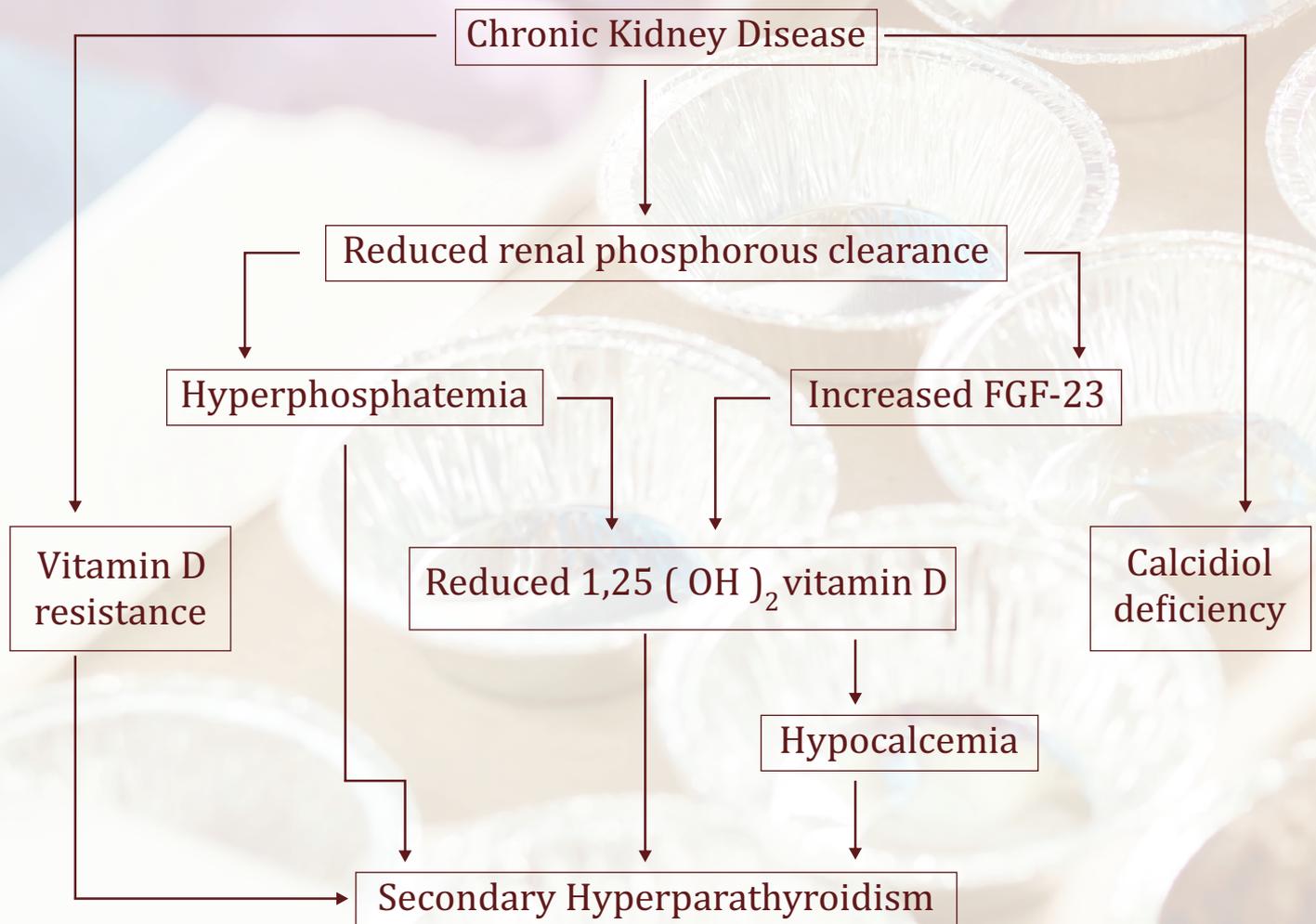
Calcitriol Injection 1mcg / ml (1 ml Amp)

La Renon

Calcitriol ($1, 25 (OH)_2$ Vitamin D) in Kidney Disease

- Calcitriol measurement is most helpful in the treatment and monitoring of chronic kidney disease (CKD).
- A deficit of calcitriol is an important factor leading to the uncontrolled secretion of parathyroid hormone (PTH) resulting in secondary hyperparathyroidism (2-HPTH).
- Decreased functioning proximal tubule cells leads to a decrease in calcitriol which decreases intestinal calcium absorption, leading to hypocalcemia.
- As the ionized calcium (iCa) decreases, the secretion of PTH is stimulated.
- The excess PTH effectively resorbs bone in an attempt to raise iCa, resulting in bone loss.
- Calcitriol therapy is used in CKD to prevent the development of 2-HPTH, and also as a treatment.

Role of Vitamin D in the development of secondary hyperparathyroidism in CKD



Clinical Evidence :

Low-dose intravenous calcitriol treatment of secondary hyperparathyroidism in hemodialysis patients

- Intravenous calcitriol is known to directly suppress PTH secretion and release.
- Effect of four months of treatment with low-dose intravenous calcitriol on PTH levels in 83 hemodialysis patients was evaluated.
- The criteria for including patients in the study were a serum PTH levels at least four times the normal limit, a serum total calcium less than 10 mg/dl and good control of the serum phosphorus level.
- All patients underwent standard bicarbonate or acetate dialysis; dialysate calcium level was maintained at the usual 3.5 mEq/liter concentration.
- Initial calcitriol dose was 0.87 ± 0.02 (SEM) $\mu\%$ (0.015 $\mu\text{g}/\text{kg}$ body wt) thrice weekly at the end of dialysis, and it was reduced in case of hypercalcemia or elevated calcium-phosphate product. Seven out of 83 patients dropped out during treatment.

Results :

- Among the 76 patients who completed the study, 58 (76%) showed a highly significant decrease of intact PTH levels (average reduction 48%) and of alkaline phosphatase levels after four months of therapy.
- Total serum calcium increased slightly but significantly in the responder group but remained unchanged in the non-responders.
- No significant changes in ionized calcium levels could be detected, even in responders.
- Treatment was well tolerated by patients, but 60% of them had transient episodes of hyperphosphatemia.
- Mean serum phosphate was 4.95 mg/dl at the beginning of the study.
- It increased significantly after four months of treatment in patients who showed a decrease of PTH levels, although it remained within acceptable limits, below 5.5 mg/dl.
- Twenty-eight of 76 patients (37%) reduced the dose of calcitriol because their calcium phosphate products exceeded 60.

Conclusion :

- Low-dose intravenous calcitriol therapy for secondary hyperparathyroidism in dialysis patients is safe and may be highly effective in reducing serum PTH and alkaline phosphatase levels without significant increases of ionized calcium concentrations.
- However, the frequent occurrence of asymptomatic hyperphosphatemia indicates that similar precautions are needed for intravenous and oral calcitriol administration.

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Description :

Calcitriol is believed to be the most active form of Vitamin D3 or biologically active Vitamin D in stimulating intestinal calcium and phosphate transport. One USP unit or one IU of Vitamin D activity is equal to 0.025 mcg vitamin D (1 mg = 40,000 units). Laretol contains calcitriol 0.25 mcg Soft Gelatin capsules and Laretol Injection contains calcitriol 1 mcg.

Indication :

- **Laretol capsule** is indicated in the management of secondary hyperparathyroidism & resultant metabolic bone disease in patients with moderate to severe chronic renal failure not yet on dialysis.
- **Laretol Injection** is indicated for the management of hypocalcemia in patients undergoing chronic renal dialysis.

Mechanism of Action :

Calcitriol or the biologically active Vitamin D metabolites control the intestinal absorption of dietary calcium, the tubular reabsorption of calcium by the kidney, and, in conjunction with parathyroid hormone (PTH), the mobilization of calcium from the skeleton. They act directly on bone cells (osteoblasts) to stimulate skeletal growth and on the parathyroid glands to suppress PTH synthesis and secretion.

Dosage :

- **Laretol** : It can be administered orally either as a capsule (0.25 mcg or 0.50 mcg).
- **Laretol Injection** : The recommended initial dose of Laretol Injection is 0.5 mcg (0.01 mcg/kg) administered three times weekly.

Presentation :

Laretol is available as a strip of 10 SG capsule in Alu-PVDC blister packing.

Laretol Injection is available as 5×1 ml Ampoules.

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