LINDACALS

Instructions for the medicinal product

Trade name: Lindacals.
International Nonproprietary Name: Alfacalcidol + Calcium Carbonate.
Dosage form: Soft gelatin capsule .
Composition: Each soft gelatin capsule contains:
Alfacalcidol BP 0.25 mcg;
Calcium Carbonate BP equivalent to Elemental Calcium 200 mg;
Excipients q.s.
Approved Colours used in capsule shell.
Pharmacotherapeutic group: Regulator of calcium and phosphorus metabolism.
ATC Classification: A12AX.
Pharmacologic property:
Alfacalcidol:
Alfacalcidol chemically known as 1α-hydroxyvitamin D3 is fat soluble and upto 100% absorption normally takes place. After absorption, alfacalcidol is rapidly hydroxylated at 2 position, predominantly in liver although the enzyme is widely distributed in body tissues. Alfacalcidol (1α-hydroxyvitamin D3) undergoes rapid hepatic conversion to 1,25-dihydroxyvitamin D3, which acts as a regulator of calcium and phosphate metabolism. Due to this rapid conversion, the therapeutic benefits of alfacalcidol are virtually the same as those of 1,25-dihydroxyvitamin D3. The main effects are to increase circulating 1,25-dihydroxyvitamin D3 levels, and thereby to increase intestinal absorption of calcium and phosphate, promote bone mineralisation, regulate plasma parathyroid hormone levels as well as to decrease bone resorption, with relief from bone and muscle pain.
Elemental Calcium (Calcium Carbonate):
Calcium carbonate is converted to calcium chloride by hydrochloric acid in stomach where 39% of it is absorbed. It is absorbed as free calcium and bicarbonate ions and is not metabolised.
Physiological concentrations of calcium are rightly controlled principally by the effect of parathyroid hormone (PTH), vitamin D and its metabolites and calcitonin on intestinal absorption, deposition in bone and renal excretion.
RATIONALE OF COMBINATION:
Alfacalcidol increases the intestinal absorption of calcium. If calcium is readily available in the same preparation, much better and proper absorption of calcium will occur. Calcium supplementation along with alfacalcidol has shown to have a beneficial effect in osteoporosis.
Calcium supplementation is usually done with 0.5 - 2g per day of calcium carbonate, gluconate, lactate etc. The calcium content of calcium carbonate is 40% and 500 mg calcium carbonate contains 200 mg elemental calcium which is the least recommended dose of calcium. Moreover, the dosage of alfacalcidol will be reduced to some extent. So, this combination is pharmacoeconomic and beneficial for the patient.
Indications for use:
- Osteoporosis;
- Renal bone disease (Renal osteodystrophy);
- Hypoparathyroidism;
- Hyperparathyroidism (with bone disease);
- Rickets;
- Osteomalacia;
- Chronic renal failure;
- Conditions associated with gastric hyperacidity.

Contraindications:
- Hypersensitivity to the compositon or to any of the excipients of product;
- Presence of hypercalcaemia;
- Hyperphosphataemia (except when occuring with hypoparathyroidism) or hypermagnesaemia;
- Renal calculi;
- Nephrolithiasis;
- Zollinger's Ellison Syndrome;
- Concomitant digoxin therapy.

Pregnancy and Nursing Mother:
There is insufficient evidence which establishes the safety of alfacalcidol and calcium carbonate use during pregnancy. As with all drugs, alfacalcidol should only be used during pregnancy if treatment is essential and no better alternative is available.
Although not definitely established, it is likely that increased levels of 1,25-dihydroxyvitamin D3 will be found in the breast milk of mothers treated with alfacalcidol. This might have some influence on calcium metabolism in a breast-fed infant and discontinuation of breast-feeding should be considered. There is no contraindication to the use of calcium carbonate in lactating women
Dosage and directions for use:
The dosage and administration of Lindacals should be adjusted according to the need of the patient.
The initial dosage is:
Adults: 1-2 capsules / day
Elderly patients: 1 capsule /day
The exact dosage in osteoporosis is not defined, however the various clinical studies have used the dosage of alfacalcidol in range of 0.5 - 1 mcg/day with or without calcium in treatment of osteoporosis.
Not recommended in children
Subsequent dose titration can be done according to the clinical and biochemical response so as to avoid hypercalcaemia.
Most adults respond to doses of 1 to 3 mcg/day of alfacalcidol and 0.25 - 3 gm of calcium carbonate.
Indices of response, in addition to a rise in plasma calcium, may include a progressive reduction in alkaline phosphatase, a reduction in parathyroid hormone levels, an increase in urinary calcium excretion in patients with normal renal function, bone radiography and histological improvements.
Side-effects:
Generally relate to hypercalcaemia and, in the case of renal impairment,
hyperphosphataemia which may be induced by alfacalcidol therapy. In hypercalcaemic dialysis patients, the possibility of calcium influx from the dialysate should be considered.
No other side effects associated directly with alfacalcidol therapy have been noted. Constipation may be a problem with calcium carbonate. Systemic alkalosis and hypercalcaemia are well documented.
Overdose:
Symptoms: Hypercalcaemia which may manifest clinically as malaise, fatigue, weakness, dizziness, drowsiness, headache, nausea, dry mouth, constipation, diarrhoea, heartburn, vomiting, abdominal pain, gastrointestinal discomfort, muscle pain, bone pain, joint pain, pruritus or palpitations. There are no documented cases of acute overdose of calcium carbonate.
Treatment: Administration of Lindacals should be stopped if hypercalcaemia occurs.
Severe hypercalcaemia may require treatment with general supportive measures, with intravenous fluids, and if needed, with a loop diuretic or corticosteroids.
In acute overdosage, early treatment with gastric lavage and / or the administration of mineral oil may reduce absorption and promote faecal elimination.
Drug interactions:
Alfacalcidol
Alfacalcidol / Digitalis Glycosides : Hypercalcaemia in patients taking digitalis preparations may precipitate cardiac arrhythmias. Patients taking digitalis concurrently with alfacalcidol must therefore be closely monitored.
Alfacalcidol/Barbiturates/Enzyme-inducing anticonvulsant Drugs : Patients on barbiturates or other enzyme-inducing anticonvulsants may require an increased dose of alfacalcidol to produce the desired effect.
Alfacalcidol / Drugs Affecting intestinal Absorption : Absorption of alfacalcidol may be impaired by concurrent use of mineral oil (prolonged use), cholestyramine, colestipol, sucralfate or large amounts of aluminium based antacids.
Alfacalcidol / Magnesium : Cautions should be exercised in the use of magnesium based antacids or laxatives for patients taking alfacalcidol who are on chronic renal dialysis. Hypermagnesaemia may occur.
Alfacalcidol / thiazides : The risk of hypercalcaemia is increased in patients taking - thiazide diuretics concurrently with alfacalcidol.
Alfacalcidol / Vitamin D and Derivatives : Alfacalcidol is a potent derivative of Vitamin D. Pharmacological doses of Vitamin D and its derivatives should not be given during alfacalcidol treatment because of the possibility of additive effects and an increased risk of hypercalcaemia.
Calcium Carbonate
Calcium carbonate may enhance cardiac effect of digoxin in case of systemic hypercalcaemia.
Calcium carbonate may interfere with absorption of concomitantly administered tetracycline and ciprofloxacin.
Cautions:
Alfacalcidol increases the intestinal absorption of calcium and phosphate, serum levels of which should be monitored, particularly in patients with renal failure. Periodic and regular monitoring of calcium, phosphate, alkaline phosphatase, magnesium and creatinine levels as well as other appropriate biochemical parameters should be done.
If hypercalcaemia or hypercalciuria occurs, this can be corrected rapidly by stopping treatment until plasma calcium levels return to normal. Lindacals may then be restarted at half the last dose used or as per response of the patient.
Lindacals should be administered with caution to patients with hypercalciuria, especially those with a history of renal calculi.
Effects on ability to drive and use machines:
Lindacals has no or negligible influence on the ability to drive or use machines.
Presentation:
3x10 PVC Blister in a monocarton, with instruction for use.
Storage:
Keep in dry place, protected from light at a temperature below 30°C. Keep out of reach of children.
Shelf life:
Labeled. Do not use after expiry date.
Distribution Condition:
Non-prescribed medicine.

Manufactured for:
BELINDA LABORATORIES PVT Ltd.
E-186, Back Room of Ground
Floor, Greater Kailash-I,
New Delhi-110048

BELINDA

Manufactured by:
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