120mm

210mm

Recalbon® 0.5mcg Tablets

(Alfacalcidol)

COMPOSITION:

Recalbon® 0.5mcg Tablets

Each tablet contains:

Alfacalcidol BP..... 0.5mcg

DESCRIPTION:

Alfacalcidol is a colorless crystalline compound with a melting range of 136°-144°C. It is sensitive to light and very soluble in methanol, ethanol and chloroform, soluble in ether, sparingly soluble in methyl formate and acetronitrile

ACTION AND CLINICAL PHARMACOLOGY:

1α-hydroxyvitamin D_3(1α-OHD_3) stimulates intestinal calcium and phosphorus absorption, the reabsorption of calcium from bone and possibly the renal reabsorption of calcium. To be effective in disorders resulting from vitamin D deficiency, vitamin D must undergo two metabolic conversions, first in the liver to 25-hydroxyvitamin D and then in the kidney to the physiologically active metabolite, 1, 25-dihydroxyvitamin D3 (1,25-$(OH)_2D_3$)

In patients with chronic renal failure, progressive nephron destruction blocks the production of 1,25-$(OH)_2$ D_3 by the kidneys resulting in diminished serum levels of this metabolite

When alfacalcidol is administered in this clinical situation, it is rapidly converted to 1,25-$(OH)_2D_3$ in the liver, effectively by passing the critical renal metabolic conversion. This hepatic conversion of alfacalcidol is accomplished very rapidly, before any stimulation of the intestine or bone occurs

The beneficial effects of alfacalcidol on the development of renal bone disease in patients with renal failure not yet undergoing dialysis has been demonstrated in a large, randomized, placebo controlled study

INDICATIONS AND CLINICAL USE:

- Osteoporosis
- Malabsorptive and nutritional rickets
- Management of hypocalcemia
- Secondary hyperparathyroidism
- Osteodystrophy in patients with chronic renal failure

CONTRAINDICATIONS:

Known hypersensitivity to 1α-hydroxyvitamin D3, vitamin D or any of its analogues and derivatives. Alfacalcidol is contraindicated when there is biochemical evidence of hypercalcemia, hyperphosphatemia, or evidence of vitamin D overdose

WARNINGS:

Alfacalcidol should not be used concomitantly with other vitamin D products or derivatives. As with all vitamin D preparations and metabolites, hypercalcemia must be anticipated when using alfacalcidol. Regular monitoring of plasma calcium is essential. Indeed, alfacalcidol should only be used when adequate facilities are available for monitoring of blood and urine chemistries on a regular basis

During treatment with alfacalcidol, the total serum calcium (mg/dL) times serum inorganic phosphate (mg/dL) PRODUCT (Ca x P) SHOULD BE MAINTAINED AT ACCEPTED LEVELS. A dialysate calcium level of 1.75mmol/L or above, in addition to excess dietary calcium supplements may lead to frequent episodes of hypercalcemia

In patients on digitalis hypercalcemia may precipitate cardiac arrhythmias. In such patients alfacalcidol should be used with extreme caution

The safety of alfacalcidol in women who are or may become pregnant has not been established; use of alfacalcidol in these cases may be considered only when the potential benefits have been weighed against possible hazards to mother and fetus. Alfacalcidol may be excreted in human milk, therefore, breast feeding during treatment should be avoided

PRECAUTIONS:

Patient selection and follow-up

The therapeutic margin with alfacalcidol is narrow; therefore, the optimal daily dose must be carefully titrated for each individual patient

The occurrence of hypercalcemia depends on such factors as the degree of bone mineralization, the state of renal function and the dose of alfacalcidol. Excessive doses of the drug induce hypercalcemia and hypercalciuria

DRUG INTERACTIONS:

Alfacalcidol should be used with extreme caution in patients on digitalis, as hypercalcemia may trigger cardiac arrhythmias. Resins such as cholestyramine and mineral oil used as a laxative may interfere with the intestinal absorption of alfacalcidol. Patients concurrently treated with barbiturates and other anticonvulsant drugs may require higher doses of alfacalcidol, as these drugs may interfere with the action of vitamin D

ADVERSE REACTIONS:

In general, the adverse effects of alfacalcidol are similar to those encountered with excessive vitamin D intake. The early and late signs and symptoms associated with vitamin D intoxication and hypercalcemia may include:

a) Early: Pruritus, weakness, headache, red-eyes, somnolence, nausea, cardiac arrhythmia, vomiting, excessive thirst, dry mouth, constipation, muscle pain, bone pain and metallic taste

b) Late: Polyuria, polydipsia, anorexia, weight loss, nocturia, conjunctivitis, corneal calcification, photophobia, rhinorrhea, pancreatitis, pruritus, hyperthermia, decreased libido, elevated BUN, albuminuria, hypercholesterolemia, elevated SGOT and SGPT, ectopic calcification, hypertension, cardiac arrhythmias and, rarely, overt psychosis

Hypercalcemia and possibly an exacerbation of hyperphosphatemia are the more frequent adverse reactions that have been reported with alfacalcidol in patients with renal osteodystrophy. Elevated levels of calcium and phosphorus increase the risk of metastatic calcification and may accelerate the decline in renal function in some patients with chronic renal failure

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SYMPTOMS AND TREATMENT OF OVERDOSAGE:
Dosages of alfacalcidol in excess of daily requirements can cause hypercalcemia, hypercalciuria and hyperphosphatemia. Conversely, a high intake of calcium and phosphate concomitantly with therapeutic doses of alfacalcidol may cause similar abnormalities

DOSAGE AND ADMINISTRATION:
Initial dose:
Children under 20kg body weight: 0.05mcg/kg/day
Adult and children above 20kg weight: 1mcg daily

It is important to adjust the dosage according to the biochemical response to avoid hypercalcaemia

The dose should be adjusted with careful monitoring of the serum Ca level

For adults:

- **Chronic liver failure and osteoporosis:**
  0.5 – 1.0mcg, as alfacalcidol is generally administered orally once a day. The dose should be adjusted according to the age of the patients and the severity of symptoms

- **Hyperthyroidism and other diseases associated with abnormal vitamin D metabolism:**
  1.0 – 4.0mcg, as alfacalcidol is generally administered orally once a day. The dose should be adjusted according to the disease, age of the patients, severity of symptoms, and the type of the diseases

OR
As directed by the physician

PRESENTATION:
Recalbon® 0.5mcg tablets in pack of 10's

STABILITY:
See expiry on the pack

INSTRUCTIONS:
Keep out of reach of children
Avoid exposure to heat, light and humidity
Store between 15 to 30°C
Improper storage may deteriorate the medicine

ریکال بون ۰٫۵ مائیکروگرام ٹیبلٹ
(الفاکیلسیڈول)

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں

بچوں کی پہنچ سے دور رکھیں

دوا کو دھوپ، گرمی، اور نمی سے محفوظ ۱۵ سے ۳۰ ڈگری سینٹی گریڈ کے درمیان میں رکھیں ورنہ دوا خراب ہو جائیگی

Manufactured by:
SAMI Pharmaceuticals (Pvt.) Ltd.
F-95, S.I.T.E., Karachi-Pakistan
www.samipharmapk.com