Bioalfa

(Alfacalcidol BP)

Tablets / Drops

گولیاں/ ڈراپس

بائیوالفا

(الفا کیلسیڈول BP)

COMPOSITION:

Bioalfa Tablets
Each film coated tablet contains:
Alfacalcidol BP … 0.25mcg, 0.5mcg & 1mcg.
[NQ's Specs.]

Bioalfa Drops
Each ml contain:
Alfacalcidol BP ... 2mcg.
[NQ's Specs.]

DESCRIPTION:

Bioalfa tablet is an active form of vitamin D_3. It is an agent for the improvement of calcium metabolism and promotion of bone formation. Alfacalcidol is directly converted into its active form 1α, 25 $(OH)_2$ D_3 in liver by 25 hydroxylase and acts on intestine, bone, kidney and parathyroid gland. As compared to vitamin D, main advantage of **Bioalfa** (Alfacalcidol) is rapid onset and reversal of action which allows an accurate dose titration and decreases the risk of prolonged hypercalcemia.

PHARMACOKINETICS:

Bioalfa (Alfacalcidol) is absorbed through small intestine and rapidly metabolized into 1α, 25 $(OH)_2$ -D_3 in liver. The peak serum level is observed in 8-24 hours after oral administration and its half life is 2-4 days in normal adults.

INDICATIONS:

Bioalfa is indicated in all conditions where there is a disturbance of calcium metabolism due to impaired 1α-hydroxylation of vitamin D_3 such as when there is reduced renal function.
The main indications are:
- Uremic bone disease.
- Hyperparathyroidism (with bone disease).
- Hypoparathyroidism.
- Post-menopausal, senile and steroid-induced osteoporosis.
- Nutritional and malabsorptive rickets and osteomalacia.
- Pseudo-deficiency (vitamin D-dependent) rickets.
- Hypophosphatemic vitamin D resistant rickets and osteomalacia.
- Prophylactic and therapeutic use in neonatal hypocalcemia.

DOSAGE:

TABLETS AND DROPS:

For all indications except osteoporosis:
Adults: 1mcg/day
Elderly patients: 0.5mcg/day
Children under 20Kg: 0.05mcg/day
Children 20Kg and over except in renal osteodystrophy: 1mcg/day
The dose of **Bioalfa**(Alfacalcidol) should be adjusted thereafter to avoid hypercalcemia. Plasma levels should initially be measured at weekly intervals. The daily dose of **Bioalfa** (Alfacalcidol) may be increased by increments of 0.5mcg. When the dose is stabilised, measurements may be taken every 2- 4 weeks. Most adults respond to doses of 1-3mcg/day. When there is biochemical or radiographic evidence of bone healing (and in hypoparathyroid patients when normal plasma calcium levels have been attained) the dose generally decreases.
Maintenance dose: The dose required for maintenance are generally in the range of 0.25 to 1mcg/day. Should hypercalcemia occur, **Bioalfa** (Alfacalcidol) should be stopped until plasma calcium returns to normal (usually about a week) then restarted at one half of the previous dose.
Osteoporosis: The usual dose of **Bioalfa** (Alfacalcidol) is 0.5mcg/day in adults. The recommended maintenance dose is 0.5-1mcg/day which should not be exceeded. The general oral dose for children with osteoporosis ranges 0.01-0.03mcg/kg once a day.
Renal Bone Disease (Renal Osteodystrophy): The dose for children 20kg and over with renal osteodystrophy is 0.04-0.08mcg/kg/day.

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Children seem to need relatively higher dose than adults and may even need the adult dose.
Hypoparathyroidism/Hyperparathyroidism: For adults 1-4mcg of **Bioalfa** (Alfacalcidol) is given orally once a day. Severe hypocalcemia is corrected more rapidly with higher doses of **Bioalfa** (Alfacalcidol) e.g. 3-5mcg, together with calcium supplements. **Bioalfa** (Alfacalcidol) can be given for 2-3 weeks as preoperative treatment for primary or tertiary hyperparathyroidism surgery.

INSTRUCTIONS FOR USAGE OF DROPS:
Half-drop doses should be rounded up to the next whole number of drops. Plasma levels should initially be measured at weekly intervals. The daily dose of **Bioalfa** may be increased by increments of 0.25-0.5mcg. When the dose is stabilised, measurements may be taken every 2-4 weeks.

CONTRA-INDICATIONS:
Hypercalcemia. Hypersensitivity to any of its constituents.

ADVERSE EFFECTS:
Adverse effects are uncommon with **Bioalfa** (Alfacalcidol). The adverse effects include hypercalcemia, nephrocalcinosis, eczema, itching, anorexia, nausea, vomiting, epigastric distress and elevation of GPT, GOT, γ-GTP, BUN & serum creatinine levels.

GENERAL PRECAUTIONS:
To avoid over dosage, the dose should be adjusted to keep the serum calcium level within normal range by periodical monitoring. If hypercalcemia occurs, treatment with **Bioalfa** should be stopped immediately until serum calcium level returns to normal (in about one week). Then the treatment should be reinitiated at a lower dose.
Serum phosphate should be monitored regularly, especially in the early stages of treatment. Caution in patients under treatment with cardioactive glycosides or digitalis.

DRUG INTERACTIONS:
Careful attention should be given to concomitant use of: Magnesium containing preparations (hypermagnesemia may occur) and Digitalis preparations.
Patients taking barbiturates or anticonvulsants may require larger doses of **Bioalfa** due to the induction of hepatic detoxification enzymes.

USE DURING PREGNANCY AND LACTATION:
Bioalfa should only be used in pregnancy and during lactation if considered essential by the physician.

INSTRUCTIONS:
Store below 30°C. Protect from heat, light and moisture. Keep out of the reach of children.

PRESENTATION:
Bioalfa Tablets 0.25mcg, 0.5mcg, 1mcg are available in the blister pack of 10's.
Bioalfa Drops are available in 20ml pack.

ہدایات:
۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔ گرمی، روشنی اور نمی سے بچائیں۔
بچوں کی پہنچ سے دور رکھیں۔

PHARMA
Manufactured by:
NABIQASIM INDUSTRIES (PVT.) LTD.
17/24, Korangi Industrial Area,
Karachi-Pakistan.
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