گولياں



الفاكيلسية ول اي د ٠٠٠ مائيكروگرا) كيلشيم كار بونبي^ن يو ايس بي • • • امليگرا)

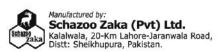
ڈاکٹری مدایات کےمطابق دواکی مقدار میں مرض اورعلامات کےمطابق رة وبدل كباجاسكتا ہے۔

بروں کے لیے:

بون کئیرسی کی عمومی خوراک ایک سے دو گولیاں روز اندہیں۔

* دوا کوشنڈی (۲۵سنٹی کریڈدرجہ ارت سے کم)اور خشک جگه بر کھیں۔ 🚜 دواکوگری،روشنی اورنمی سےمحفوظ رکھیں۔ * تمام دوائيں بچوں کی پہنچ سے دور رکھیں۔

بون کئیوسی گولهان (۱×۱۰) بلسر یک مین دستاب بن -



Bone-Care C

Alfacalcidol E.P. 0.5 µg Calcium Carbonate U.S.P. 1000 mg

COMPOSITION:

Each Bone-Care C tablet contains:

(equivalent to elemental calcium 400mg)

CLINICAL PHARMACOLOGY:

Mode of action:

Alfacalcidol is chemically known as lα-hydroxy vitamin D₃. It is a fat Anacacted is chemically known as to-hydroxy vitamin D₃, it is a fat soluble vitamin. Following an oral administration, alfacalcidol is rapidly absorbed into the blood through intestine and the 25-position of the side chain is hydroxylated with 25-hydroxylase of hepatic microsome into the final active substance, 1α, 25-(OH)₂ D₃. It binds with receptors in intestinal tract, bones and other target organs, and develops series of physiological activities, such as promotion of Calcium absorption from intesting bone resorting and hope formation activities. from intestine, bone resorption, and bone formation activities. Elemental Calcium:

Calcium carbonate is converted to calcium chloride by hydrochloric acid (HCl) in stomach where 39% of it is absorbed. It is absorbed as free calcium and bicarbonate ions.

Pharmacokinetics:

Absorption: After oral administration alfacalcidol is absorbed from gastrointestinal tract. The presence of bile is necessary for adequate intestinal absorption. Absorption may be decreased in patients with decreased fat absorption.

Absorption may be decreased in patients with decreased rat absorption. Calcium is absorbed mainly from small intestine by active transport and passive diffusion. About one third of ingested calcium is absorbed although it can vary depending upon the dietary factors and the state of the small intestine; absorption is also increased in calcium deficiency and during periods of high physiological requirements such as during childhood or pregnancy and lactation.

Distribution:

Alfacalcidol and its metabolites circulate in the blood bound to a specific

 $\alpha\text{-}$ globulin. It can be stored in adipose and muscle tissue for long periods of time. It is slowly released from such storage sites and from skin where it is formed in the presence of sunlight or ultraviolet light. Calcium crosses placenta and is distributed into breast milk. Metabolism:

Alfacalcidol is converted rapidly in the liver to calcitriol. Calcium carbonate is converted to calcium chloride by hydrochloric acid (HCl) in stomach.

Excretion:

Alfacalcidol and its metabolites are excreted mainly in the bile and faeces with only small amounts appearing in the urine. There is some enterohepatic recycling but it is considered to have negligible contribution to alfacalcidol status.

Excess calcium is predominantly excreted renally. Unabsorbed calcium is eliminated in the faeces, together with that secreted in bile and pancreatic juice. Minor amounts are lost in the sweat, skin, hair and nails.

INDICATIONS:

Bone-Care C is indicated for the treatment/management of vitamin D and calcium deficiency states such as;

- Osteoporosis
- Hypocalcaemia Hypoparathyroidism
- Typoparatny Hyperparathyroidism (with bone disease) Osteomalacia and Rickets Renal Osteodystrophy

DOSAGE & ADMINISTRATION: Adults:

The dosage should be adjusted according to the disease and symptoms of the patient. The usual dose of Bone-Care C in adults is one to two tablets daily, maintenance dose is half tablet to two tablets and in elderly patients usual dose is one tablet daily or as advised by the physician.

CONTRA-INDICATIONS:

Bone-Care C tablets are contraindicated in patients with hypersensitivity to the active substances. Bone-Care C tablets should not be administered in the presence of hypercalcaemia, hyperphosphataemia (except when occurring with hypoparathyroidism) or hypermagnesaemia, renal calculi, nephrolithiasis, Zollinger's Ellison Syndrome, concomitant digoxin

PRECAUTIONS & WARNINGS:

Bone-Care C tablets should not be given to patients with hypercalcaemia or diseases associated with hypercalcaemia (sarcoidosis and some malignancies). It should be used with caution in infants, who may have increased sensitivity to its effects, and patients with renal impairment or calculi, or heart disease, who might be at increased risk of organ damage if hypercalcaemia occurred. Plasma phosphate concentrations should be controlled during therapy with Bone-Care C. It is advised that patients receiving pharmacological doses of alfacalcidol should have their plasma calcium concentration monitored at regular intervals, especially initially or if symptoms suggest toxicity. Similar monitoring is recommended in infants if they are breast fed by mothers receiving pharmacological doses of alfacalcidol.

DRUG INTERACTIONS:

Alfacalcidol:

There is an increased risk of hypercalcaemia if alfacalcidol is given with thiazide diuretics, calcium or phosphate.

Some anti-epileptics (Carbamazepine, Phenobarbital, Phenytoin

and Primidone) may increase vitamin D requirement. Rifampicin and Isoniazid may reduce the effectiveness of alfacalcidol.

Corticosteroids may counteract the effects of alfacalcidol.

Calcium Carbonate:
- Calcium enhances the effects of digitalis glycosides on the heart

and may precipitate digitalis intoxication.

Calcium salts reduce the absorption of a number of other drugs such as bisphosphonates, fluorides, some fluoroquinolones and tetracyclines; dose should be separated by at least 3 hours.

Excessive intake of Bone-Care C leads to development of hyperphosphataemia or hypercalcaemia. Associated effects of hypercalcaemia include hypercalciuria, ectopic calcification and renal and cardiovascular damage

OVERDOSAGE & MANAGEMENT:

In cases of suspected over dosage resulting in hypercalcaemia, administration of Bone-Care C should be stopped. Many cases of adverse reactions are considered to be caused by hypercalcaemia. Therefore, in case of adverse reactions, monitoring of serum Ca level is appropriate.

Symptoms of over dosage include: anorexia, lassitude, nausea, vomiting, constipation or diarrhea, polyuria, nocturia, sweating, headache, thirst, somnolence and vertigo.

STORAGE CONDITIONS:

Store in a cool and dry place below 25°C. Protect from heat, light and moisture. Keep all medicines out of the reach of children.

Bone-Care C tablets are available in (2 x 10) blister pack.