كرونك رينل فيليئراوراوسيٹوپروسز كے ليے: بروں کے لیے ۰٠٠ تا ا مأتکر وگرام الفاکیلسیڈول دن میں ایک مرتبد تاہم علامات کی شدت اورمریض کی عمرکو مُنظرر کھتے ہوئے خوراک میں ردوبدل کیا جاسکتا ہے۔ ما ئېرىيرا تھائروۋ زم اورغىرمعمولى وئامن ۋى مىنابولزم سے دابسة بياريوں كے ليے: بروں کے لیے اتام مائیکروگرام الفاکیلسیڈول دن میں ایک مرتبه۔ تاہم مریض کی عمر،علامات کی شدت اور بیاری کی قتم کو مذنظر رکھتے ہوئے خوراک میں ردوبدل کیا جاسکتا ہے۔ بچوں کے لیے: ڈاکٹر کی ہدایات کے مطابق استعال کریں۔

- * دوا کوځمنڈی اورخشک جگه بررکمیں۔
- * دواکوگری،روشنی اورنی مے محفوظ رکھیں۔ * تمام دوائیں بچوں کی پہنچ سے دورر کھیں۔

. بون کیز ۲۵- مانگروگرام گولیان (۱×۱۰) ایلو ایلوبلسٹر پیک میں دستیاب ہیں۔ بون کیئر۵۰۰ مائیکروگرام گولیاں (۱×۱۰) ایلو _ایلوبلسٹر یک میں دستیاب ہیں _

Manufactured by: **Schazoo Zaka (Pvt) Ltd.** Kalalwala, 20-Km Lahore-Jaranwala Road, Distt: Sheikhupura, Pakistan.

Bone-Care®

Alfacalcidol E.P. 0.25 µg and 0.5 µg

Active Form of vitamin D3

COMPOSITION:

Each Bone-Care 0.25µg tablet contains: Alfacalcidol E.P...... 0.25µg. Each Bone-Care 0.5µg tablet contains: Alfacalcidol E.P.....

CLINICAL PHARMACOLOGY:

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 micro some into the final active substance, 1 α , 25-(OH)₂ D₃. It binds with receptors in intestinal tract, bone and the other target organs, and develops series of physiological activities, such as promotion of Calcium absorption from intestine, bone resorption, and bone formation activities.

INDICATIONS AND USAGE:

Bone-Care is used for the improvement of various symptoms (hypocalcemia, tetany, bone pain, bone lesions, etc) due to abnormal vitamin D metabolism in the following conditions:

- Chronic renal failure
- Hypoparathyroidism
- Vitamin D-resistant rickets and osteomalacia
- Osteoporosis

DOSAGE AND ADMINISTRATION:

The dose should be adjusted with careful monitoring of the serum

Chronic renal failure and osteoporosis: For adults, 0.5- $1.0~\mu g$ as alfacalcidol once a day. The dose should be adjusted according to the age of the patients and the severity of

Hypoparathyroidism and other diseases associated with

abnormal vitamin **D** metabolism: For adults, 1.0-4.0 µg as alfacalcidol once a day. The dose should be adjusted according to the disease, age of the patients, severity

of the symptoms and the type of the diseases.

Dosage for the children:

The general oral dose for children with osteoporosis ranges 0.01-0.03µg/kg as alfacalcidol once a day, and that for the other indications ranges 0.05-0.1µg/kg as alfacalcidol once a day. The dose should be adjusted according to the diseases and the symptoms.

PRECAUTIONS & WARNINGS:

To avoid overdose, the dose should be adjusted to keep the serum Ca level within normal range by the periodical monitoring. In case of hypercalcemia, treatment with alfacalcidol should be stopped immediately. After the serum Ca level returns to normal, the treatment shall be re-initiated at a lower dose.

DRUG INTERACTIONS:

Careful attention should be paid to concomitant use. Magnesium-containing preparations (Hypermagnesemia is reported

Digitalis preparations (in case hypercalcemia is caused by alfacalcidol, the activity of digitalis preparations may be increased to cause arrhythmia).

USE IN PREGNANCY:

Because of the potential for adverse effects on the nursing infant, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

PEDIATRIC USE:

Pediatric use needs care to avoid overdose, by gradual dose increase after initial lower dose under close monitoring of serum Ca level, urinary Ca/Cr Ratio.

ELDERLY USE:

Attention to the dose should be required due to generally lower physiologic functions.

SIDE EFFECTS:

(Rarely: <0.1%, infrequently: 0.1-<5%, no specific designation: >5% or frequency unknown).

Gastrointestinal: Anorexia, nausea/vomiting, abdominal distention, diarrhea, constipation, stomach pain, and/or stomach discomfort may infrequently occur. Dyspepsia, oral cavity discomfort and thirst may rarely occur.

Psychoneurologic:

Headache/dull headache, insomnia/feeling irritated, weakness/malaise, dizziness, feeling of numbness, sleepiness, failure of memory, tinnitus, presbycusis, back pain, shoulder stiffness, feeling of spasticity of the lower limb and/or chest pain may rarely

Cardiovascular: Slight increase of blood pressure and/or palpitation may rarely occur.

Hepatic: Elevation of Glutamic-Oxaloacetic Transaminase (GOT), Glutamic-Pyruvic Transaminase (GPT), Lactate Dehydrogenase (LDH), and/or gamma-Guanosine Triphosphate (ã-GTP) may infrequently occur.

Renal: Elevation of Blood Urea Nitrogen (BUN) and/or sCr (indicating decreased renal function) and renal calculus may rarely occur.

Dermatologic: Itching and/or rash may infrequently occur. Hot feeling may rarely occur.

Ophthalmic: Conjunctival congestion may infrequently occur. Osseous: Ectopical calcification (calculus) around joints may rarely

Others: Edema and/or hoarseness may rarely occur.

OVERDOSAGE:

Many cases of adverse reactions are considered to be caused by hypercalcemia. Therefore, in case of adverse reactions, monitoring of serum Ca level is appropriate.

STORAGE CONDITIONS:

- Store in cool and dry place.
- Protect from heat, light and moisture.
- Keep all medicines out of the reach of the children.

Bone-Care 0.25 µg tablets are available in (1x10) Alu-Alu blister pack. Bone-Care 0.5 µg tablets are available in (1x10) Alu-Alu blister pack.