كاليدم يفل جن كاكرينين كليم لس ٣٥٠- ٧٠ لى لفرقى مند عوان كيليد خوداك شي ردوبدل ضرور کی بیا ہے۔ تا ہم شدید تکلیف عل جا اگردے کے مریضوں علی بیدوامنو عب مدایات: اورتھونید + علی گرام_ ہفتہ دارا یک کولی ۱) ہفتہ بھی اس دن کا انتخاب کریں جو آپ کے روز مرہ کے معمولات بھی سب نے یاد مورد را ہو۔ اس ختب شدہ دن بھی مجمع ہونے کے بعد کوئی بھی غذا، چاہے یا کی بھی اور دوا کے لینے سے پہلے ٢) افي مع كمعمولات جارى وكل _ آب ينف كلة بيل _ كدر وسكة بيل يامل بالركات بيل-



Séhazoo Zaka (Pvt) Latelyala 20-Km Lahor s-Jaranni Lately ale, 20-Km Lahore-Jaranwala Ricad, Distt Sheikhupura, Pakistan.

COMPOSITION:

Each tablet contains; Alendronate Sodium U.S.P. equivalent to 70 mg alendronic acid.

CLINICAL PHARMACOLOGY:

Osteoporosis is characterized by low bone mass that leads to an increased risk of fractures usually of spine, hip and wrist. Alendronate is a bisphosphonate that binds to bone hydroxyapatite and specifically inhibits the activity of osteoclasts, the boneresorbing cells. The osteoclasts adhere normally to the bone surface but lack the ruffled border that is indicative of active resorption. Alendronate does not interfere with osteoclast attachment, but it does inhibit osteoclast activity. It reduces bone resorption with no direct effect on bone formation, although this process reduces ultimately because bone resorption and formation are coupled during bone turnover.

INDICATIONS AND USAGE:

Orthonate is indicated for

- The treatment and prevention of osteoporosis in postmenopausal
- Treatment to increase bone mass in men with osteoporosis.

DOSAGE AND ADMINISTRATION:

The usual recommended dose is 1 Tablet with a full glass of water once a week upon arising for the day at least 30 minutes before the first food, drink or other oral medications and the patients should not lie down for at least 30m inutes after dose. It should not be taken at bed time or before arising of the day. Failure to follow these instructions may increase the risk of esophageal adverse experience. Patients should receive supplemental calcium and vitamin D, if dietary intake is inadequate. No dosage adjustment is necessary for the elderly or for the patients with mild to moderate renal insufficiency (creatinine clearance 35-60 ml/min). Alend ronate is not recommended for patients with more severe renal insufficiency (creatinine clearance <25ml/min).

CONTRA-INDICATIONS:

- Orthonate is contra-indicated in Patients
- With esophageal abnormalities such as stricture, a chalasia or
- inability to remain stand up right for 30 min. after dosing.
- Hypersensitive to any component of this product. - Hypo calcemia, Pregnancy, lactation.

PRECAUTIONS & WARNINGS:

General precautions:

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ed by				ed bythe upper g such as	gastrointestinal mucosa	, esophageal adverse r	eactions,
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PAG esophagitis, esophageal ulcers and esophageal erosions have been USE IN ELDERLY PATIENTS: reported in patients receiving treatment with Alendronate. Therefore There is no age-related difference in safety and efficacy profile. precautions for physician as well as for patient is necessary which however greater sensitivity of some older individual cannot be ruled are as follows: Precautions at physician stage: DRUG INTERACTIONS - Physicians should be alert to any signs or symptoms causing a Estrogen/hormone replacement therapy (HRT): Degree of possible esophageal reactions and should instruct the patients to suppression of bone turnover is greater with the concurrent use of discontinue Alendronate and seek medical attention if they develop Alendronate and HRT than with either component alone. dysphagia, odynophagia, retrosternal pain or new or worsening he artburn. - Alendronate is not recommended for patients with creatinine Calcium supplements/Antacids: clearance <35 m L/m in. Concurrent administration will interfere with absorption of - Causes of osteoporosis other than estrogen deficiency and aging Alendronate. Therefore patients must wait at least 30min. after should be considered. Hypoicalcemia must be corrected before initiating therapy with As pirin: The incident of upper gastrointestinal adverse events is Alendronate. - Other disturbances of mineral metabolism (such as vitamin D greater in patients receiving concurrent therapy of Alendronate and deficiency) should also be effectively treated. Aspirin containing products. NSAIDs: Caution should be taken during concomitant use with Alendronate because NSAIDS use is associated with ga strointe stinal irritation. Precautions at patient stage: The risk of severe esophageal adverse experiences appears to be greater in patients who lie down after taking Alendronate and/or who fail to swallow it with a full glass of water, and/or who continue to Alendronate is well tolerated & side effects are usually mild and take Alendronate after developing symptoms suggestive of esophageal imitation. Therefore, it is very important that the full Gastrointes tinal Tract: Abdominal pain, nausea, dyspepsia, dosing instructions are provided to, and understood by the patient. To facilitate delivery to the stomach and thus reduce the potential constipation diarrhoea, flatulence, acid regurgitation, esophageal ulcer, vomiting, dysphagia, abdominal distention and gastritis. for e sophage all irritation patients should be instructed to swallow Alendronate with a full glass of water and not to lie down for at least 30 minutes and until after their first food of the day. - Patients should not chew or suck on the tablet because of a Mus culoskele tal: potential for oropharyngeal ulceration. Bone, muscle, or joint pain and muscle cramp. - Patients should be specifically instructed not to take Alendronate at bedtime or before arising for the day.
- Patients should be informed that failure to follow these instructions may increase their risk of esophageal problems. Patients should be Directions for patients: instructed that if they develop symptoms of esophageal disease Choose the day of the week that best fits your schedule. (such as difficulty or pain upon swallowing, retrostemal pain or new Upon awaking, before taking your first food, beverage or other or worsening heartburn) they should stop taking Alendronate and medication, take one tablet with a full glass of plain water. consult their physician 2. Continue your morning activities. - Patients should be instructed that if they miss a dose of Don't lie down, eat, drink or take other medication for at least 30 Alendronate once weekly, they should take one tablet on the morning after they remember. They should not take two tablets on the same minutes after dose. Then you may eat breakfast. 3. Take Orthona & ARGINTERED TAKE Orthona & ARGINTERED TO THE YOUR MISS & COMPANY OF THE THEORY OF THE THE THEORY OF THE THEORY OF THE THEORY OF THE THEORY OF THE THEORY should return to taking one tablet once a week, as originally scheduled on their chosen day. after you remember. Don't take two table ts on the same day. Return to taking one tablet once a week, as originally scheduled on your chosen day. STORAGE INSTRUCTIONS: PREGNANCY:

Alendronate should be used in pregnancy only if the potential benefit

* Store in a cool and dry place. Approx Protect from heat, light and moisture justifies the potential risk to mother and fetus. ed by *Keep all medicines out of the reach of children. NURSING MOTHERS: PACKING: Because of the potential for adverse effects on the nursing infant, a ppop Quethonate tablets are a yailable in (1x4) Aly Alu pack. 64€ision should be made whether to discontinue nursing or œ Scontinue the drug (\$200) into account the high france of the drug (\$200) 200 0000 2010000 the mother.

PEDIATRIC USE:

Safety and effectiveness in pediatric patients have not been

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