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گولیاں

اورتھونیٹ® ۷۰ ملی گرام

الینڈرونیٹ سوڈیم یو۔ایس پی

اوسٹیوپروسس

خوراک:

اورتھونیٹ کی معمولی خوراک ایک گولی ہفتہ میں ایک دفعہ ہے، جو کہ صبح ہوتے ہی اور ناشتہ/شربت یا کوئی دوا کھانے سے کم از کم ۳۰ منٹ پہلے ایک گلاس پانی سے لینی چاہیے۔ دوا کھانے کے بعد کم از کم ۳۰ منٹ تک نہیں لیٹنا چاہیے۔ یہ دوا رات کو یا دن نکلنے سے پہلے ہرگز نہیں لینی چاہیے۔ مزید ہدایات کردے کے لیے مریض جن کا کریٹنائن کلیئرنس ۳۵-۶۰ ملی لیٹر فی منٹ ہو ان کیلئے خوراک میں ردوبدل ضروری نہیں ہے۔ تاہم شدید تکلیف میں مبتلا گردے کے مریضوں میں یہ دوا متوقع ہے۔

ہدایات: اورتھونیٹ ۷۰ ملی گرام۔ ہفتہ وار ایک گولی

۱) ہفتہ میں اس دن کا انتخاب کریں جو آپ کے روزمرہ کے معمولات میں سب سے زیادہ موزوں ہو۔ اس منتخب شدہ دن میں صبح ہونے کے بعد کوئی بھی غذا، چائے یا کسی بھی اور دوا کے لینے سے پہلے اورتھونیٹ ۷۰ ملی گرام کی گولی سادہ پانی کے ایک گلاس کے ساتھ لے لیں۔

۲) اپنی صبح کے معمولات جاری رکھیں۔ آپ بیٹھ سکتے ہیں، کھڑے رہ سکتے ہیں یا چل پھر سکتے ہیں۔ صرف پتیل نہ ہیں کہ آپ کو لیٹنا نہیں ہے۔ یہ بہت اہم ہے۔ آدھ گھنٹے کے بعد آپ سب کچھ کھا سکتے ہیں۔

۳) یاد رکھیں کہ اورتھونیٹ آپ کو ہفتہ میں ایک دفعہ لینی ہے اور ہفتہ کا دن لینی ہے جس دن کا آپ نے انتخاب کیا تھا۔ اگر آپ کو کوئی دوا لینا بھول گئے ہیں تو جب آپ کو یاد آئے تو اس کے بعد اگلی صبح ایک گولی لے لیں۔ ایک دن میں دو گولیاں بالکل نہ لیں۔ اس کے بعد ہفتہ میں ایک دن دوا لینے کے شیڈول پر واپس آجائیں جو کہ آپ کے شیڈول کے مطابق منتخب شدہ دن ہے۔

پیکنگ: اورتھونیٹ ۷۰ ملی گرام گولیاں (۴×۷) ایلومینیم بلیک پیک میں دستیاب ہیں۔

Manufacturer
Sehazoo Zaka (Pvt) Ltd.
Site: 20-KM, Lahore-Jaranwala Road,
Distt: Sheikhupura, Pakistan.

Orthonate®

Alendronate Sodium

ONE TABLET WEEKLY

Tablets

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 bone-resorbing 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 women.
- 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 30minutes 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). Alendronate is not recommended for patients with more severe renal insufficiency (creatinine clearance <35 ml/min).

CONTRA-INDICATIONS:
Orthonate is contra-indicated in Patients
- With esophageal abnormalities such as stricture, achalasia or inability to remain stand upright for 30 min. after dosing.
- Hypersensitive to any component of this product.
- Hypocalcemia, Pregnancy, lactation.

PRECAUTIONS & WARNINGS:
General precautions:
As with other bisphosphonates Alendronate may cause local irritation of the upper gastrointestinal mucosa, esophageal adverse reactions, such as esophagitis, esophageal ulcers and esophageal erosions have been reported in patients receiving treatment with Alendronate. Therefore precautions for physician as well as for patient is necessary which are as follows:

Precautions at physician stage:
- Physicians should be alert to any signs or symptoms causing a possible esophageal reactions and should instruct the patients to discontinue Alendronate and seek medical attention if they develop dysphagia, odynophagia, retrosternal pain or new or worsening heartburn.
- Alendronate is not recommended for patients with creatinine clearance <35 mL/min.
- Causes of osteoporosis other than estrogen deficiency and aging should be considered.
- Hypocalcemia must be corrected before initiating therapy with Alendronate.
- Other disturbances of mineral metabolism (such as vitamin D deficiency) should also be effectively treated.

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 take Alendronate after developing symptoms suggestive of esophageal irritation. Therefore, it is very important that the full dosing instructions are provided to, and understood by the patient.
- To facilitate delivery to the stomach and thus reduce the potential for esophageal 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 potential for oropharyngeal ulceration.
- 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 instructed that if they develop symptoms of esophageal disease (such as difficulty or pain upon swallowing, retrosternal pain or new or worsening heartburn) they should stop taking Alendronate and consult their physician.
- Patients should be instructed that if they miss a dose of Alendronate once weekly, they should take one tablet on the morning after they remember. They should not take two tablets on the same day but
should return to taking one tablet once a week, as originally scheduled on their chosen day.

PREGNANCY:
Alendronate should be used in pregnancy only if the potential benefit justifies the potential risk to mother and fetus.

NURSING MOTHERS:
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:
Safety and effectiveness in pediatric patients have not been established.

Edited by							
R&D MANAGER 3.0±0.5°C	RND MANAGER 3.0±0.5°C	Q.C. MANAGER 3.0±0.5°C	Q.A. MANAGER 3.0±0.5°C	PRODUCT MANAGER 3.0±0.5°C	MARKETING MANAGER 3.0±0.5°C	CHIEF PHARMACIST 3.0±0.5°C	CE

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USE IN ELDERLY PATIENTS:
There is no age-related difference in safety and efficacy profile, however greater sensitivity of some older individual cannot be ruled out.

DRUG INTERACTIONS:
Estrogen/hormone replacement therapy (HRT): Degree of suppression of bone turnover is greater with the concurrent use of Alendronate and HRT than with either component alone.

Calcium supplements/Antacids:
Concurrent administration will interfere with absorption of Alendronate. Therefore patients must wait at least 30min. after dose.
Aspirin: The incident of upper gastrointestinal adverse events is greater in patients receiving concurrent therapy of Alendronate and Aspirin containing products.
NSAIDs: Caution should be taken during concomitant use with Alendronate because NSAIDS use is associated with gastrointestinal irritation.

SIDE EFFECTS:
Alendronate is well tolerated & side effects are usually mild and rare:
Gastrointestinal Tract: Abdominal pain, nausea, dyspepsia, constipation diarrhoea, flatulence, acid regurgitation, esophageal ulcer, vomiting, dysphagia, abdominal distention and gastritis.

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Musculoskeletal:
Bone, muscle, or joint pain and muscle cramp.

Directions for patients:
1. Choose the day of the week that best fits your schedule.
Upon awaking, before taking your first food, beverage or other medication, take one tablet with a full glass of plain water.
2. Continue your morning activities.
Don't lie down, eat, drink or take other medication for at least 30 minutes after dose. Then you may eat breakfast.
3. Remember your chosen day.
Take Orthonate once a week on the morning that you have chosen.
If you miss a dose, take one tablet on the morning after you remember. Don't take two tablets on the same day. Return to taking one tablet once a week, as originally scheduled on your chosen day.

STORAGE INSTRUCTIONS:
* *Store in a cool and dry place.*
Protect from heat, light and moisture.
* *Keep all medicines out of the reach of children.*

PACKING:
Orthonate tablets are available in (1x4) Alu-Alu pack.

TO BE SOLD ON PRESCRIPTION OF A REGISTERED MEDICAL PRACTITIONER ONLY.

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