

Lendomax[®]

Alendronic Acid Tablets 70 mg

Composition:

Each tablet contains: Alendronate Sodium Trihydrate equivalent to Alendronic Acid 70 mg.

Excipients: Microcrystalline cellulose, lactose anhydrous, croscarmellose sodium and magnesium stearate.

Properties:

Alendronate Sodium Trihydrate is a bisphosphonate that inhibits osteoclast bone resorption with no direct effect on bone formation. Preclinical studies have shown preferential localisation of alendronate to sites of active resorption. Activity of osteoclasts is inhibited, but recruitment or attachment of osteoclasts is not affected. The bone formed during treatment with alendronate is of normal quality.

Distribution: 28 L (exclusive of bone). Protein binding: ~ 78%.

Metabolism: there is no evidence that alendronate is metabolized in humans. Bioavailability: Fasting: Female: 0.7%, reduced 60% with food or drink. Half-life elimination: Exceeds 10 years.

Excretion: urine, feces (as unabsorbed drug).

Indications:

Lendomax is indicated for the treatment of postmenopausal osteoporosis.

Lendomax reduces the risk of vertebral and hip fractures.

Contraindications:

Lendomax is contraindicated for patients with known hypersensitivity to any of its component.

Abnormalities of the oesophagus and other factors which delay oesophageal emptying such as stricture or achalasia.

Inability to stand or sit upright for at least 30 minutes.

Hypocalcaemia.

Precautions:

There are no adequate data for the use of alendronate in pregnant and lactating women, therefore it should not be used.

No effects on ability to drive and use machines have been observed.

Interaction with other drugs:

If taken at the same time, it is likely that food and beverages (including mineral water), calcium supplement, antacids, and some oral medicinal products will interfere with absorption of alendronate. Therefore, patients must wait at least 30 minutes after taking alendronate before taking any other oral medicinal products.

Increased risk of hypocalcaemia when bisphosphonates given with aminoglycosides.

Absorption of bisphosphonates reduced by oral iron.

Warnings:

Caution should be used when alendronate is given to patients with active upper gastro-intestinal problems, such as dysphagia, symptomatic oesophageal disease, gastritis, duodenitis, ulcers, or with a recent history (within the previous year) of major gastrointestinal disease such as peptic ulcer, or active gastro-intestinal bleeding, or surgery of the upper gastrointestinal tract other than pyloroplasty. Correct disturbances of calcium and mineral metabolism (e.g. vitamin-D deficiency, hypocalcaemia) before starting and monitor serum-calcium concentration during treatment, consider dental check-up before initiating bisphosphonate (risk of osteonecrosis of the jaw), exclude other causes of osteoporosis, atypical stress fractures reported (discontinue unless benefits of continued treatment clearly outweigh risks).

It is very important that the full dosing instructions are provided to and understood by the patients, because failure to follow these instructions may increase their risk of oesophageal problems.

Patients should be instructed that if they miss a dose of Lendomax once weekly, they should take one tablet in 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.

Alendronate is not recommended for patients with renal impairment where GFR is less than 35 ml/min.

Dosage and Administration:

The recommended dosage is one 70 mg tablet once weekly. Lendomax must be taken at least 30 minutes before the first food, beverages, or medicinal product of the day with plain water only.

Lendomax should only be swallowed upon arising for the day with a full glass of water.

Patients should not chew the tablet or allow the tablet to dissolve in their mouths because of a potential for oropharyngeal ulceration.

Patients should not lie down until after their first food of the day which should be at least 30 minutes after taking the tablets.

Patients should not lie down for at least 30 minutes after taking Lendomax.

Lendomax should not be taken at bedtime or before arising for the day.

Patients should take supplemental calcium and vitamin D if dietary intake is inadequate.

No dosage adjustments is necessary for the elderly, and for renal impaired patients with GFR greater than 35 ml/min.

Overdosage:

Hypocalcaemia, hypophosphatemia, and upper gastrointestinal adverse events, such as upset stomach, heartburn, oesophagitis, gastritis, or ulcer, may result from oral over dosage.

Milk or antacid should be given to bind alendronate. Owing to the risk of oesophageal irritation, vomiting should not be induced and the patient should remain fully upright.

Side Effects:

Oesophageal reactions (Severe oesophageal reactions (oesophagitis, oesophageal ulcers, oesophageal stricture and oesophageal erosions) have been reported, patients should be advised to stop taking the tablets and to seek medical attention if they develop symptoms of oesophageal irritation such as dysphagia, new or worsening heartburn, pain on swallowing or retrosternal pain), abdominal pain and distension, dyspepsia, regurgitation, melena, diarrhoea or constipation, flatulence, musculoskeletal pain, headache, rarely rash, pruritus, erythema, photosensitivity, uveitis, scleritis, transient decrease in serum calcium and phosphate, nausea, vomiting, gastritis, peptic ulceration, hypersensitivity reactions (including urticaria and angioedema), and atypical stress fractures with long-term use also reported, myalgia, malaise, and fever at initiation of treatment, very rarely severe skin reactions (including Stevens-Johnson Syndrome), osteonecrosis of the jaw. Consult your Pharmacist or Physician if any side effect is observed.

Pharmaceutical Precautions:

Keep at room temperature (15-30°C).

Do not use beyond the expiry date or if the product shows any sign of deterioration.

Presentations:

Lendomax Tablets are available as packs of 4 tablets each.

Hospital packs are available.

® is a trademark.

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
 - Strictly follow the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
 - The doctor and the pharmacist are experts in medicine, its benefits and risks.
 - Do not by yourself interrupt the period of treatment prescribed for you.
 - Do not repeat the same prescription without consulting your doctor.
- Keep medicament out of reach of children.

Council of Arab Health Ministers & Union of Arab Pharmacists.



Manufactured by:
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