



RAM PHARMA

Bonmax®

(Alendronate Sodium)

Description:

Bonmax (Alendronate Sodium) is an alendronate monosodium salt trihydrate, that in animal studies localize preferentially to sites of bone resorption. Specifically under osteoclasts, and inhibits osteoclastic bone resorption with no direct effect on bone formation.

Indications:

Bonmax is indicated for the treatment of osteoporosis in postmenopausal women.

Dosage and administration: The recommended dosage of **Bonmax** is 10mg once a day.

Instruction for the patient:

- Bonmax** must be taken with a full glass of plain water only at least half an hour before the first meal, since other beverages (including mineral water) food and some medications are likely to reduce the absorption of alendronate then reduced it's effects.
- Patients should not chew the tablet or allow the tablet to dissolve in their mouths.
- Patients should not lie down for at least 30 minutes after taking the tablets. (Patient should sit down or stand up when they take this medicine so as to make it easy for the medicine to go down to the stomach and to avoid any esophageal problem)
- Bonmax** should not be taken at bed time or before arising.
- No dosage adjustment is necessary for patients with mild-to-moderate renal insufficiency (creatinine clearance 35 to 60 ml /min).
- No dosage adjustment is necessary for patients with liver function abnormalities.

Contraindications:

- Hypersensitivity to any component of the tablet.
- Hypocalcemia
- Abnormalities of the esophagus which delay esophageal emptying such as stricture .
- Inability to stand or sit upright for at least 30 minutes.

Special warnings and precautions:

- Esophagitis, esophageal ulcer and esophageal erosions have been reported in patients receiving treatment with **Bonmax**. In some cases these have been severe and required hospitalization. So Patients should be instructed to discontinue this drug and to seek medical attention if they develop any of the following symptoms: dysphagia, odynophagia, retrosternal pain and heartburn.
- Patients should be informed that failure to follow dosing instructions may increase their risk of esophageal problems.
- Caution should be used when **Bonmax** is given to patients with active upper gastrointestinal problems such as dysphagia, esophageal diseases gastritis, duodenitis, or ulcers.

Renal insufficiency: **Bonmax** is not recommended for patients with severe renal insufficiency (creatinine clearance less than 35 ml per minute. Impaired calcium and mineral metabolism:

Hypocalcemia should be corrected before initiating therapy with this drug.

Use during pregnancy and lactation:

Alendronate has not been studied in pregnant women and is only indicated for the treatment of osteoporosis in postmenopausal women (pregnancy category C).

Use in children: **Bonmax** should not be used in children.

Drug interactions:

- Patients must wait at least for half an hour after taking **Bonmax** before taking any other oral medication (particularly calcium supplement and antacids).
- The concomitant use of hormone replacement therapy and alendronate for the treatment of osteoporosis in postmenopausal woman has not been specifically studied.

Adverse effects:

Mild side effects: Abdominal pain, dyspepsia, esophageal ulcer, dysphagia, and abdominal distention.

Rare side effects: Rash, erythema, musculoskeletal pain, constipation or diarrhea, flatulence, and headache.

Side effects reported in post marketing use: esophagitis, esophageal erosions, and esophageal ulcer.

Presentation: **Bonmax** Tablets: Each tablet contains Alendronate sodium eq. to 10 mg Alendronic acid.

Blister packs of 10, 20 and 30 tablets.

Bonmax product is a trade mark for RAM pharmaceutical - Jordan.

Some presentations may not be available in all countries.

Storage: store below 30° C.

This is a Medicament :

- Keep all medicaments out of reach of children.
- A medicament is a product that affects your health, and its consumption contrary to instructions is dangerous.
- Strictly follow the doctor's prescription, the method of use and the instructions of the pharmacist who dispensed the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not interrupt the treatment before consulting your doctor.
- Do not repeat the same prescription without consulting your doctor.