

Once-Weekly
RAFOMAX[®]
(Alendronate Sodium)
ALENDRONIC ACID 70MG TABLETS

RAFOMAX[®] ALENDRONATE IS USED FOR TREATING OSTEOPOROSIS IN MEN AND POSTMENOPAUSAL WOMEN. IT ALSO IS USED FOR PAGET'S DISEASE OF BONE AND OSTEOPOROSIS CAUSED BY STEROID TREATMENT. NON-FDA APPROVED (OFF-LABEL) USES INCLUDE VITAMIN D OVERDOSE AND OSTEOPOROSIS CAUSED BY SPINAL INJURY.

The recommended dose is **Rafomax**[®] (Alendronate Sodium) alendronic acid 70mg tablets one 70 mg tablet per week. The optimal duration of bisphosphonate treatment for osteoporosis has not been established. The need for continued treatment should be re-evaluated periodically based on the benefits and potential risks of Alendronic Acid on an individual patient basis, particularly after 5 or more years of use.

To permit adequate absorption of alendronate:

Alendronic Acid 70mg Tablets must be taken at least 30 minutes before the first food, beverage, or medicinal product of the day with plain water only. Other beverages (including mineral water), food and some medicinal products are likely to reduce the absorption of alendronate.

To facilitate delivery to the stomach and thus reduce the potential for local and oesophageal irritation/adverse experiences:

- Alendronic Acid 70mg Tablets should only be swallowed upon arising for the day with a full glass of water (not less than 200 ml or 7 fl.oz.).
- Patients should only swallow Alendronic Acid 70mg Tablets whole. Patients should not crush or 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 tablet.
- Patients should not lie down for at least 30 minutes after taking Alendronic Acid 70mg Tablets.
- Alendronic Acid 70mg Tablets should not be taken at bedtime or before arising for the day.

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

Use in the elderly: In clinical studies there was no age-related difference in the efficacy or safety profiles of alendronate.

Therefore no dosage adjustment is necessary for the elderly.