Abbreviated Prescribing Information

Buffered Binosto® Alendronic acid 70 mg

Binosto 70mg effervescent tablets Abbreviated Prescribing Information

Please refer to the Summary of Product Characteristics (SmPC) before prescribing Binosto.

Binosto: Each effervescent tablet contains alendronate sodium trihydrate equivalent to 70 mg alendronic acid.

Indication: Treatment of postmenopausal osteoporosis. Reduces the risk of vertebral and hip fractures.

Dosage and Administration: One 70 mg effervescent tablet once weekly. If a dose is missed, take one effervescent tablet in the morning after remembering. Do not take two tablets on the same day. Instead, return to taking one tablet per week, as originally scheduled. Periodically re-evaluate the need for continued treatment on an individual patient basis, particularly after 5 or more years of use. No dosage adjustment is necessary for the elderly. For oral use. Dissolve in half a glass of plain water. Ensure complete dissolution before drinking, stir if necessary. Consume solution when in a seated or upright position. Drink a further 30 ml or more of plain water following consumption of the solution.

Take immediately after waking, at least 30 minutes before the first food, beverage, or medicinal product of the day. Do not chew or dissolve in the mouth. Do not lie down for at least 30 minutes after taking.

Contraindications: Hypersensitivity to alendronate or other ingredients, 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.

Do not use during pregnancy or breastfeeding.

Warnings and Precautions: Contains sodium. Not recommended for patients with renal impairment where GFR is less than 35 ml/min. Not recommended for use in children below 18 years. Use caution in conditions affecting the upper GI tract. Discontinue use in cases of oesophageal reaction. Use caution in cases with a history of cancer therapy, IV administered bisphosphonates and dental disease due to increased risk of osteonecrosis of the jaw. Encourage good oral hygiene.

During bisphosphonate treatment patients should be advised to report any thigh, hip or groin pain and any patient presenting with such symptoms should be evaluated for an incomplete femur fracture.

Undesirable effects: Very commonly pain in the bones, muscles or joints, which may be severe. Commonly headache, dizziness, vertigo, disorders affecting the GI tract, alopecia, pruritus, joint swelling, asthenia, peripheral oedema. Severe skin reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis. Osteonecrosis of the jaw, atypical subtrochanteric and diaphyseal femoral fractures. For a full list of side effects, refer to the Summary of Product Characteristics.

Post-authorization Safety Study: A prospective, non-interventional, single-arm, safety study was conducted in post-menopausal women (n= 1084) treated with Binosto 70 mg effervescent tablets who were followed in routine clinical practice for 12 months (±3 months). The cumulative incidence of all related upper GI adverse events (AEs) was 9.6% (8.0% mild, 1.5% moderate, 0.2% of severe intensity). There have been no reports of oesophagitis, oesophageal or gastric ulcer and duodenitis, nor of upper GI perforation, haemorrhage or stenosis. No serious side effects related to Binosto 70 mg effervescent tablets were observed. The mean time on Binosto was 12.8 months. The mean overall compliance based on the number of tablets missed was 94.8%.

Legal Category: POM.

Pack size: Binosto 70mg effervescent tablet x 4 – NHS price £11.60

MA Number: PL40861/0006

MA Holder: Internis Pharmaceuticals Ltd., Linthwaite Laboratories, Linthwaite, Huddersfield, HD7 5QH, UK.

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Adverse events should be reported. Reporting forms and information can be found at: www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Thornton and Ross Limited by emailing thorntonross@medinformation.co.uk or by calling 01484 848164.