Prescribing information can be found at the end

36%
list price reduction
to support the NHS*

DISSOLVED

Addressing the challenges of GI tolerability and adherence to bisphosphonates with a buffered, soluble, effervescent alendronate tablet formulation[1,2]

Buffered Binosto® Alendronic acid **70 mg**

A concerning picture...

Fragility fractures place a substantial burden on the NHS[3]

1 fracture/minute[3]

1,444 fractures/day[3]

527,000 fragility fractures in 2019[3]

>£5 billion in direct healthcare costs[3]

1 in 5 women die within the first year of a hip fragility fracture[4]

A persistent problem...

Low persistence with oral bisphosphonate therapy significantly hinders prevention efforts[5]

Persistence is crucial to realise clinical benefits and reduce the fracture risk[6]

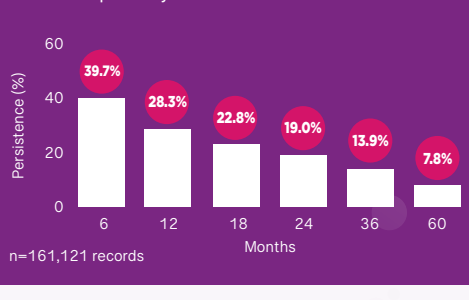
Time to benefit from bisphosphonate therapy:[7]

12.4 months
to prevent 1 nonvertebral fracture /100 postmenopausal women with osteoporosis

n=23,384 postmenopausal women

However, 2 in 3 postmenopausal women in the UK discontinue their oral bisphosphonate therapy within a year:[8]

Persistence with oral bisphosphonates within UK primary care[8]



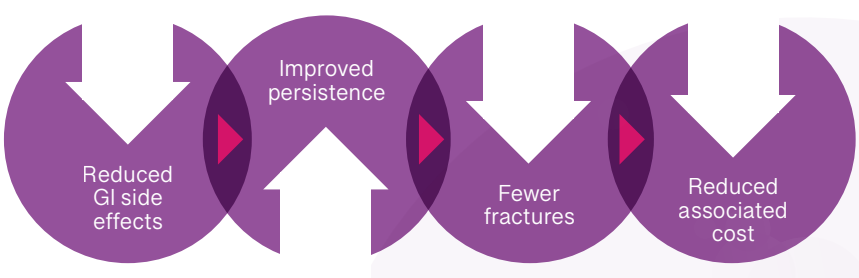
n=161,121 records

Upper GI side effects are a principal reason for stopping oral bisphosphonate treatment[9,10]

GI side effects† may account for 40% of oral bisphosphonate discontinuation[10,11]

†heartburn, acid reflux or 'other'

Minimising GI side effects has the potential to improve health outcomes[12]

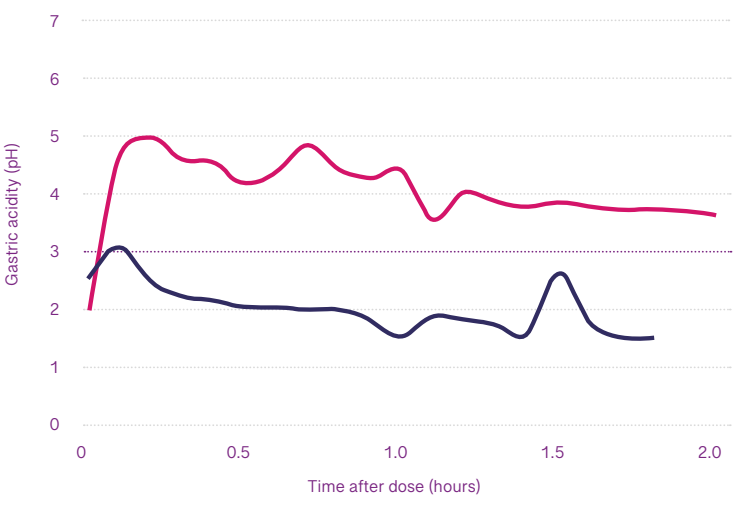


A different approach...

Binosto offers a novel solution- effervescent, buffered alendronate[12]

After taking Binosto, gastric pH levels are rapidly buffered to >3[12]

Gastric acidity curves after conventional alendronate tablets and Binosto in an example subject[13]



Single centre, open label, randomised, two-way crossover study in 12 healthy female volunteers (18-60 years)

3 dosing days separated by ≥7 days to allow for washout of drug

Exposure to alendronate at pH <3 is irritating to gastro-oesophageal tissue[14]

Binosto

Conventional alendronate tablets

Adapted from Hodges[13]

A real improvement...

Distinctive pharmacologic properties deliver enhanced upper GI tolerability[2]

2021 Real-world study

Postmenopausal women treated with Binosto experienced few upper GI adverse events:[2]

Cumulative incidence of all upper GI AEs related to Binosto was 9.6%

No serious upper GI AEs related to Binosto were reported

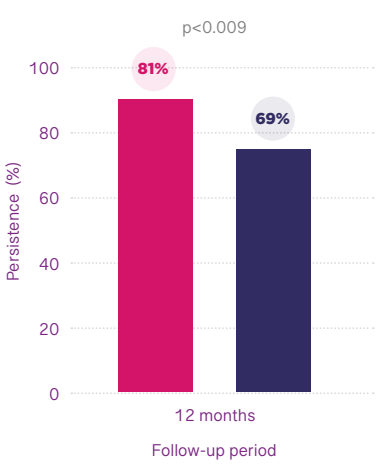
63%
of patients at a UK clinic who had reported side effects to tablet forms of risedronate and alendronate reported good tolerability with Binosto and were happy to continue therapy long-term[14]

Improved tolerability supports greater persistence[1]

In this real-world study, over 80% of patients presented with a prevalent major osteoporotic fracture which may have resulted in a higher motivation than normal to persist[1]

However, a notable and significant difference was still evident between alendronate formulations:[1]

Increased persistence with Binosto[1]



Retrospective analysis of 360 postmenopausal women with T-score below -2.5, or between -2 and -2.5 with ≥1 vertebral fracture, attending two bone clinics in northern Italy

144 received Binosto and a randomly selected and age-matched historical cohort of 216 received conventional alendronate tablets

Binosto n=144

Conventional alendronate tablets n=216

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Addressing the challenges of GI tolerability and adherence to bisphosphonates with a buffered, soluble, effervescent alendronate tablet formulation[1,2]

Buffered Binosto® Alendronic acid **70 mg**

Effervescent, buffered alendronate | **Improved GI tolerability[2]** | **Greater persistence[1]**

Prescribing Information

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.

Date of preparation: March 2023.

Unique ID no. BINO-15

References:
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AE: adverse event
GI: gastrointestinal
NHS: National Health Service

* Price reduction live from July 2021. Available at: mims.co.uk/drugs/endocrine/osteoporosis-other-bone-disorders/binosto Accessed on: 13.04.23

UK-BINO-27 Date of Preparation: May 2023

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