

Binosto® Once Weekly 70 mg Effervescent Tablets

(alendronic acid)

Read all of this leaflet carefully before you start taking this medicine, because it contains important information for you, even if this is a repeat prescription.

- * Keep this leaflet. You may need to read it again.
- * If you have any further questions, ask your doctor or pharmacist or nurse.
- * This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- * If you get any of the side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- 1 What Binosto is and what it is used for
- 2 What you need to know before you take Binosto
- 3 How to take Binosto
- 4 Possible side effects
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- 6 Contents of the pack and other information

1 What Binosto is and what it is used for

What is Binosto?

Alendronate, the active substance of Binosto belongs to a group of non-hormonal medicines called bisphosphonates. Binosto prevents the loss of bone that occurs in women after they have been through the menopause, and helps to rebuild bone. It reduces the risk of spine and hip fractures.

What is Binosto used for?

Your doctor has prescribed Binosto to treat your osteoporosis. Binosto reduces the risk of spine and hip fractures.

Binosto is a once weekly treatment.

What is osteoporosis?

Osteoporosis is a thinning and weakening of the bones. It is common in women after the menopause. At the menopause, the ovaries stop producing the female hormone, oestrogen, which helps to keep a woman's skeleton healthy. As a result, bone loss occurs and bones become weaker. The earlier a woman reaches the menopause, the greater the risk of osteoporosis.

Early on, osteoporosis usually has no symptoms. If left untreated, however, it can result in broken bones.

Although these usually hurt, breaks in the bones of the spine may go unnoticed until they cause height loss. Broken bones can happen during normal, everyday activity, such as lifting, or from minor injury that would not generally break normal bone. Broken bones usually occur at the hip, spine, or wrist and can lead not only to pain but also to considerable problems like stooped posture ('dowager's hump') and loss of mobility.

How can osteoporosis be treated?

Osteoporosis can be treated and it is never too late to begin treatment. Binosto not only prevents the loss of bone but actually helps to rebuild bone you may have lost and reduces the risk of bones breaking in the spine and hip.

As well as your treatment with Binosto, your doctor may suggest you make changes to your lifestyle to help your condition, such as:

Stopping smoking: Smoking appears to increase the rate at which you lose bone and, therefore, may increase your risk of broken bones.

Exercise: Like muscles, bones need exercise to stay strong and healthy. Consult your doctor before you begin any exercise programme.

Eating a balanced diet: Your doctor can advise you about your diet or whether you should take any dietary supplements (especially calcium and Vitamin D).

2 What you need to know before you take Binosto

Do not take Binosto

- (1) if you are allergic (hypersensitive) to alendronate or any of the other ingredients of this medicine (listed in section 6).
- (2) if you have certain problems with your gullet (oesophagus - the tube that connects your mouth with your stomach) such as narrowing or difficulty swallowing.
- (3) if you cannot stand or sit upright for at least 30 minutes.
- (4) if your doctor has told you that you have low blood calcium.

If you think any of these apply to you, do not take the effervescent tablets. Talk to your doctor first and follow the advice given.

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Binosto if

- * you suffer from kidney problems
- * you have any swallowing or digestive problems
- * your doctor has told you that you have Barrett's oesophagus (a condition associated with changes in the cells that line the lower oesophagus)
- * you have been told you have low blood calcium
- * you have poor dental health, gum disease, a planned extraction or you don't receive routine dental care
- * you have cancer

- * you are undergoing chemotherapy or radiotherapy
- * you are taking corticosteroids (such as prednisone or dexamethasone)
- * you are or have been a smoker (as this may increase the risk of dental problems).

You may be advised to have a dental check-up before starting treatment with Binosto.

It is important to maintain good oral hygiene when being treated with Binosto. You should have routine dental check-ups throughout your treatment and you should contact your doctor or dentist if you experience any problems with your mouth or teeth such as loose teeth, pain or swelling.

Irritation, inflammation or ulceration of the gullet (oesophagus - the tube that connects your mouth with your stomach) often with symptoms of chest pain, heartburn, or difficulty or pain upon swallowing may occur, especially if patients do not use enough water to dissolve the effervescent tablet and/or if they lie down less than 30 minutes after taking Binosto. These side effects may worsen if patients continue to take Binosto after developing these symptoms.

Children and adolescents

Binosto should not be given to children and adolescents.

Other medicines and Binosto

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

It is likely that calcium supplements, antacids, and some oral medicines will interfere with the absorption of alendronate if taken at the same time. Therefore, it is important that you follow the advice given in section 3. How to take Binosto.

Taking Binosto with food and drink

It is likely that food and beverages (including mineral water) will make Binosto less effective if taken at the same time. Therefore, it is important that you follow the advice given in section 3. How to take Binosto.

Pregnancy, breast-feeding and fertility

Binosto is only intended for use in postmenopausal women. You should not take Binosto if you are or think you may be pregnant, or if you are breast-feeding.

Driving and using machines

There have been side effects (including blurred vision, dizziness and severe bone, muscle or joint pain) reported with alendronate that may affect your ability to drive or operate machinery. Individual responses to alendronate may vary (see section 4. Possible side effects).

Binosto contains sodium

This medicinal product contains 26.2 mmol (or 602.54 mg) sodium per dose. This should be taken into consideration by patients on a controlled sodium diet.

3 How to take Binosto

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Binosto must be dissolved in half a glass of plain water before taking. Do not chew or swallow the tablet whole.

Take **one** Binosto effervescent tablet **once a week, as an oral solution**

Follow these instructions carefully to make sure you will benefit from Binosto.

- 1) Choose the day of the week that best fits your schedule. Every week, take one Binosto effervescent tablet as an oral solution on your chosen day.

It is very important to follow instructions 2), 3), 4) and 5) to help the Binosto effervescent tablet as an oral solution reach your stomach quickly and help reduce the chance of irritating your gullet (oesophagus – the tube that connects your mouth with your stomach).

- 2) After getting up for the day and before taking any food, drink, or other medicine, dissolve your Binosto effervescent tablet in half a glass of plain water (not less than 120 ml or 4.2 fl.oz) (not mineral water). Once the fizzing has subsided and the effervescent tablet has completely dissolved to give a clear, colourless solution, drink this solution, followed by at least 30 ml (one sixth of a glass) of plain water. You may take additional water.

In case you perceive any undissolved tablet material, you may stir the solution until it is clear and colourless.

- * Do not take with mineral water (still or sparkling).
- * Do not take with coffee or tea.
- * Do not take with juice or milk.

Do not swallow the undissolved effervescent tablet or chew the effervescent tablet or allow it to dissolve in your mouth.

- 3) Do not lie down — stay fully upright (sitting, standing or walking) — for at least 30 minutes after drinking the oral solution containing the dissolved effervescent tablet. Do not lie down until after your first food of the day.
- 4) Do not take Binosto at bedtime or before getting up for the day.
- 5) If you develop difficulty or pain upon swallowing, chest pain, or new or worsening heartburn, stop taking Binosto and contact your doctor.

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6) After drinking the oral solution containing the dissolved Binosto effervescent tablet, wait at least 30 minutes before taking your first food, drink, or other medicine of the day, including antacids, calcium supplements and vitamins. Binosto is effective only if taken when your stomach is empty.

If you take more Binosto than you should

If you take too many effervescent tablets by mistake, drink a full glass of milk and contact your doctor immediately. Do not make yourself vomit, and do not lie down.

If you forget to take Binosto

If you miss a dose, just take one effervescent tablet dissolved in plain water on the morning after you remember, following the aforementioned instructions 2), 3), 4,) 5) and 6). *Do not take two effervescent tablets for oral solution on the same day.* Return to taking one effervescent tablet for oral solution once a week, as originally scheduled on your chosen day.

If you stop taking Binosto

It is important that you continue taking Binosto for as long as your doctor prescribes the medicine. Binosto can treat your osteoporosis only if you continue to take the effervescent tablets dissolved in plain water. If you have any further questions on the use of this, medicine ask your doctor or pharmacist or nurse.

4 Possible side effects

Like all medicines, Binosto can cause side effects, although not everybody gets them.

All medicines can cause allergic reactions, although serious allergic reactions are very rare. You should stop taking Binosto and tell your doctor immediately if you get any of the following symptoms:

- * Sudden wheeziness, difficulty in breathing, swelling of the eyelids, face, throat, tongue, lips, rash or itching (especially affecting your whole body).
- * a rash made worse by sunlight; blistering or other effects on the skin, eyes, mouth or genitals, itching or high temperature (symptoms of severe skin reactions called Stevens-Johnson syndrome or toxic epidermal necrolysis).

If you have difficulty and/or pain when swallowing, you feel pain behind the breastbone or new or worsened heartburn, stop taking Binosto and contact your doctor. If you ignore these symptoms and continue to take your effervescent tablet, as an oral solution it is likely that these gullet reactions may get worse.

The following side effects have been reported:

Very Common (may affect more than 1 in 10 people)

- * bone, muscle and/or joint pain which is sometimes severe

Common (may affect up to 1 in 10 people):

- * heartburn; difficulty swallowing; pain upon swallowing; ulceration of the gullet (oesophagus – the tube that connects your mouth with your stomach) which can cause chest pain, heartburn or difficulty or pain upon swallowing
- * joint swelling
- * abdominal pain; uncomfortable feeling in the stomach or belching after eating; constipation; full or bloated feeling in the stomach; diarrhoea; flatulence
- * hair loss; itching
- * headache; dizziness
- * tiredness; swelling in the hands or legs

Uncommon (may affect up to 1 in 100 people):

- * nausea; vomiting
- * irritation or inflammation of the gullet (oesophagus – the tube that connects your mouth with your stomach) or stomach
- * black or tar-like stools
- * blurred vision; pain or redness in the eye
- * rash; redness of the skin
- * transient flu-like symptoms, such as aching muscles, generally feeling unwell and sometimes with fever usually at the start of treatment
- * taste disturbance

Rare (may affect up to 1 in 1,000 people):

- * allergic reactions such as hives; swelling of the face, lips, tongue and/or throat, possibly causing difficulty breathing or swallowing
- * symptoms of low blood calcium levels including muscle cramps or spasms and/or tingling sensation in the fingers or around the mouth
- * stomach or peptic ulcers (sometimes severe or with bleeding)
- * narrowing of the gullet (oesophagus – the tube that connects your mouth with your stomach)
- * rash made worse by sunlight; severe skin reactions
- * pain in the mouth, and/or jaw, swelling or sores inside the mouth, numbness or a feeling of heaviness in the jaw, or loosening of a tooth. These could be signs of bone damage in the jaw (osteonecrosis) generally associated with delayed healing and infection, often following tooth extraction. Contact your doctor and dentist if you experience such symptoms.
- * unusual fracture of the thigh bone particularly in patients on long-term treatment for osteoporosis may occur rarely. Contact your doctor if you experience pain, weakness or discomfort in your thigh, hip or groin as this may be an early indication of a possible fracture of the thigh bone.
- * mouth ulcers when the tablets have been chewed or sucked.

Very Rare (may affect up to 1 in 10,000 people):

- * Talk to your doctor if you have ear pain, discharge from the ear, and/or an ear infection. These could be signs of bone damage in the ear.

Tell your doctor or pharmacist promptly about these or any other unusual symptoms.

It will help if you make a note of what you experienced, when it started and how long it lasted.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects, you can help provide more information on the safety of this medicine. HPRA Pharmacovigilance Earlsfort Terrace IRL - Dublin 2 Tel: +353 1 6764971 Fax: +353 1 6762517 Website: www.hpra.ie e-mail: medsafety@hpra.ie

5 How to store Binosto

Keep this medicine out of the sight and reach of children.

Do not use Binosto after the expiry date which is stated on the carton and the strip after EXP. The expiry date refers to the last day of that month. This medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect from moisture. Do not remove the effervescent tablets from the strip until you are ready to take the medicine.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6 Contents of the pack and other information**What Binosto contains**The active substance is:

Alendronate sodium trihydrate

Each effervescent tablet contains 70 mg alendronic acid as 91.37 mg of alendronate sodium trihydrate.

The other ingredients are:

Sodium dihydrogen citrate, citric acid anhydrous, sodium hydrogen carbonate, sodium carbonate anhydrous, strawberry flavour [maltodextrin (maize), arabic gum, propylene glycol (E 1520), nature-identical flavouring substances], acesulfame potassium, sucralose.

What Binosto looks like and contents of the pack

Binosto is available as round, white to off-white, flat faced effervescent tablets of 25 mm diameter and with beveled edges. After dissolution of the tablet the solution is clear and colourless.

The effervescent tablets are supplied in strips of composite foil. Each strip contains 2 effervescent tablets packed in individual units. The strips are packed in cartons in pack size of 4 effervescent tablets.

Procured from within the EU and repackaged by the Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

Manufacturer

Temmler Pharma GmbH, Temmlerstrasse 2, 35039 Marburg, Germany

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Blind or partially sighted?

Is this leaflet hard to see or read?

Phone Lexon (UK) Limited, Tel: +44 (0)1527 505414 for help.

This medicinal product is authorized in the Member States of the EEA under the following names:

DE	Binosto® 70 mg Brausetabletten
EL	Binosto® 70 mg Αναβράζον δισκίο
ES	Binosto® 70 mg comprimidos efervescentes
FR	Steovess® 70 mg Comprimé effervescent
IE	Binosto® Once Weekly 70 mg Effervescent Tablets
IT	Binosto® 70 mg Compresse effervescenti
PT	Binosto® 70 mg comprimidos efervescentes
RO	Binosto® 70 mg, Comprimat efervescent
UK	Binosto® 70 mg Effervescent Tablets