

PACKAGE LEAFLET: INFORMATION FOR THE USER
Binosto® 70mg effervescent tablets
(alendronic acid)

Your medicine is known as the above but will be referred to as Binosto throughout the remainder of this leaflet.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, 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 side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- It is particularly important to understand the information in section 3 before taking this medicine.

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
5. How to store Binosto
6. Contents of the pack and other information

1. WHAT BINOSTO IS AND WHAT IT IS USED FOR

Binosto is an effervescent tablet containing the active substance alendronic acid (commonly called alendronate) and 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.

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

- if you are allergic (hypersensitive) to alendronate or any of the other ingredients of this medicine (listed in section 6).
- if you have certain problems with your gullet (oesophagus – the tube that connects your mouth with your stomach) such as narrowing or difficulty swallowing.
- if you cannot stand or sit upright for at least 30 minutes.
- 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, pharmacist or nurse before taking Binosto if

- you suffer from kidney problems
- you have, or recently had 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 trouble absorbing minerals in your stomach or intestines (malabsorption syndrome),
- 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 angiogenesis inhibitors (such as bevacizumab, or thalidomide) which are used in the treatment of cancer,

- you are taking corticosteroids (such as prednisone or dexamethasone) which are used in the treatment of such conditions as asthma, rheumatoid arthritis, and severe allergies,
- 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 less than 18 years of age.

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.

Certain medicines for rheumatism or long-term pain called NSAIDs (e.g. aspirin or ibuprofen) might cause digestive problems. Therefore, caution should be used when these medicines are taken at the same time as Binosto.

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.

Pregnancy and breast-feeding

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 (for example blurred vision, dizziness and severe bone, muscle or joint pain) reported with alendronate that may affect your ability to drive or operate machinery. (see section 4).

Binosto contains sodium

This medicine contains 603 mg sodium (main component of cooking/table salt) per dose. This is equivalent to 30% of the recommended maximum daily dietary intake of sodium for an adult. 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.

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, to slightly cloudy 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 at the bottom of the glass, you may stir the solution until it is dissolved.

- 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.