

## Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

## Binosto

### Effervescent Tablets

#### Active ingredient and its quantity:

Each soluble tablet contains:

sodium alendronate trihydrate equivalent to 70 mg alendronic acid

Inactive ingredients and allergens: See section 2 "Important information about some of this medicine's ingredients" and section 6 "Additional information".

**Read the entire leaflet carefully before you start using this medicine.** This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

This medicine is not intended for children and adolescents below the age of 18.

#### 1. What is this medicine intended for?

- For treatment of osteoporosis in postmenopausal women to prevent fractures.
- For treatment to increase bone mass in men with osteoporosis.

**Binosto is a once weekly treatment.**

**Therapeutic group:** bisphosphonates (non-hormonal drug class).

#### What is osteoporosis

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

At the early stages, osteoporosis is usually asymptomatic. However, if left untreated, the condition can result in bone fractures. Although bone fractures in the spine are usually accompanied by pain, they may remain undiagnosed until height loss occurs. Bone fractures can occur during normal everyday activity such as lifting, or from minor injury that would not usually lead to fracture of a healthy bone. Bone fractures usually occur at the hip, spine or wrist, and can lead not only to pain, but also to more notable problems, such as stooped posture (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 bone loss, but actually helps to rebuild the bone, and also reduces the risk of bone fractures in the spine and hip.

Along with the treatment with Binosto, your doctor may suggest you make changes in your lifestyle to improve your condition, such as:

**Stopping smoking:** Smoking appears to increase the rate of bone loss, and, therefore, may increase the risk of bone fractures.

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

**A balanced diet:** Your doctor can advise you about your diet or the need to take any dietary supplements (especially calcium and vitamin D).

#### 2. Before using the medicine

##### Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient (alendronic acid) or any of the other ingredients in this medicine (see section 6).
- You have certain problems with the oesophagus, such as narrowing or difficulty swallowing.
- You cannot stand or sit upright for at least 30 minutes.
- Your doctor has told you that you have low blood calcium levels.

##### Special warnings about using this medicine

- **Before treatment with Binosto, tell your doctor if:**
  - You have kidney problems
  - You have, or have recently had, any digestive or swallowing problems
  - Your doctor has told you that you have Barrett syndrome (a condition associated with changes in the cells in the lower oesophagus)
  - You have been told that you have difficulty absorbing minerals in the stomach or intestines (malabsorption)
  - You have been told that you have low blood calcium levels
  - 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 for treatment of cancer
  - You are taking corticosteroids (such as prednisone or dexamethasone), which are used for treatment of asthma, rheumatoid arthritis and severe allergies
  - You are or have been a smoker (this may increase the risk of dental problems).

Irritation, inflammation or ulceration of the oesophagus may often occur, with symptoms of chest pain, heartburn, or difficulty or pain upon swallowing, especially in patients who do not use enough water to dissolve the effervescent tablet and/or in patients who lie down less than 30 minutes after taking Binosto. These side effects may worsen if patients continue taking Binosto after developing these symptoms.

##### Tests and follow up

Your doctor may advise you to undergo a dental check-up before starting treatment with Binosto.

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

##### Drug interactions

**If you are taking or have recently taken other medicines, including non-prescription medications and dietary supplements, tell your doctor or pharmacist.** Particularly if you are taking:

- Calcium supplements, antacids and certain oral medicines; these may interfere with the absorption of this medicine if taken at the same time. Therefore, it is important to follow the instructions in section 3 "How to use this medicine?".

- Certain medicines for treatment of rheumatism or prolonged pain called NSAIDs (such as acetylsalicylic acid or ibuprofen); these may cause gastrointestinal problems. Therefore, caution should be used if these medicines are taken at the same time with Binosto.

#### Using this medicine and food

It is likely that food and beverages (including mineral water) will make Binosto less effective if consumed at the same time. Therefore, it is important to follow the instructions in section 3 "How to use this medicine?".

#### Pregnancy and breastfeeding

Binosto is intended for use only in postmenopausal women. Do not take Binosto if you are pregnant or think that you are pregnant, or if you are breastfeeding.

#### Driving and using machines

Side effects (including blurred vision, dizziness and severe bone, muscle or joint pain) reported with this medicine may affect your ability to drive or operate machines. (see section 4 "Side effects").

#### Important information about some of this medicine's ingredients

Binosto effervescent tablet contains sodium. This should be taken into consideration by patients on a low-sodium diet. Each effervescent tablet contains 603 mg sodium, which is equivalent to 30% of the recommended maximum daily intake of sodium for an adult.

#### 3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

**The medicine must be dissolved in half a glass of tap water before use. Do not chew or swallow the tablet whole.**

**Only your doctor will determine your dose and how you should take this medicine. The recommended dosage is usually:**

One effervescent tablet once a week as an oral solution.

##### Do not exceed the recommended dose.

Follow the following instructions carefully:

- a. Choose the day of the week that is most suitable for your schedule. Every week, take one Binosto effervescent tablet as an oral solution on the chosen day.

It is very important to follow instructions b., c., d. and e. to help the medicine (as an oral solution) reach the stomach quickly and to help reduce the risk of oesophagus irritation.

- b. After getting up in the morning and before eating, drinking or taking any other medicine, dissolve the Binosto effervescent tablet in half a glass of tap water (not less than 120 ml) (not mineral water). Once the fizzing has subsided and the effervescent tablet has completely dissolved into a clear to slightly cloudy solution, drink the solution, followed by at least 30 ml (one sixth of a glass) of tap water. You may drink additional tap water.

If you see undissolved tablet portions, you may stir the solution until they are 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 an undissolved effervescent tablet or chew an effervescent tablet or allow the tablets to dissolve in your mouth.**

- c. Do not lie down. Stay fully upright (sitting, standing or walking) for at least 30 minutes after drinking the solution containing the dissolved effervescent tablet. Do not lie down until after eating the first meal of that day.

- d. Do not take Binosto at bedtime or before getting up in the morning.

- e. If you experience difficulty or pain upon swallowing, chest pain, new or worsening heartburn, stop taking Binosto and contact your doctor.

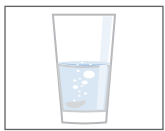
- f. After drinking the solution containing the dissolved Binosto effervescent tablet, wait at least 30 minutes before first eating, drinking or taking any other medicine on that day, including antacids, calcium supplements and vitamins. Binosto is effective only if taken on an empty stomach.

##### How to take the Binosto effervescent tablet



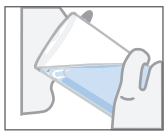
1

The effervescent tablets are supplied in strips of 2 tablets, with one tablet in each unit. Open one unit as indicated by the mark.



2

Dissolve the Binosto effervescent tablet in half a glass of tap water (not less than 120 ml).



3

Drink the solution immediately once the fizzing has subsided and the effervescent tablet has completely dissolved, followed by at least one sixth of a glass of tap water.

**If you have accidentally taken a higher dose, drink a full glass of milk and contact your doctor immediately.** Do not induce vomiting and do not lie down.

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

**If you forget to take this medicine, take one effervescent tablet dissolved in tap water on the morning after you remember.** Follow the aforementioned instructions b., c., d., e. and f. Do not take two effervescent tablets as oral solution on the same day. Continue taking one effervescent tablet as oral solution once a week, as originally scheduled on the chosen day.

Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop treatment with the medicine without consulting your doctor.

#### If you stop taking this medicine

It is important that you continue taking Binosto for as long as your doctor prescribes the medicine. Since it is not known how long you should take Binosto, consult your doctor periodically to discuss the need to continue the treatment with Binosto and to determine whether the medicine is still appropriate for you.

**Do not take medicines in the dark! Check the label and dose every time you take a medicine. Wear glasses if you need them.**

**If you have any further questions about using this medicine, consult your doctor or pharmacist.**

#### 4. Side effects

Like with all medicines, using Binosto may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

**Contact your doctor immediately** if you notice any of the following symptoms, which may be serious, due to which you may need urgent medical treatment:

**Common side effects (affect up to 1 in 10 patients):**

- Heartburn; difficulty swallowing; pain upon swallowing; oesophageal ulcer which may cause chest pain, heartburn, difficulty swallowing or pain upon swallowing

**Rare side effects (affect up to 1 in 1,000 patients):**

- Allergic reactions such as hives; swelling of the face, lips, tongue and/or throat, which can cause difficulties breathing or swallowing; severe skin reactions
- Pain in the mouth and/or jaw, swelling or sores in the mouth, numbness or sensation of heaviness in the jaw, or loosening of a tooth. These effects may be signs of bone damage in the jaw (osteonecrosis), which are usually associated with delayed healing and infection, mostly following tooth extraction. Contact your doctor and dentist if you experience these symptoms
- Unusual fracture of the thigh bone may occur rarely, especially in patients undergoing long-term treatment for osteoporosis. Contact your doctor if you experience pain, weakness or discomfort in the thigh or groin, as this may be an early indication of a possible fracture of the thigh bone

**Other side effects include:**

**Very common side effects (affect more than 1 in 10 patients):**

- Bone, muscle and/or joint pain which is sometimes severe.

**Common side effects (affect up to 1 in 10 patients):**

- Joint swelling
- Abdominal pain; sensation of abdominal discomfort or bloating after eating; constipation; sensation of fullness or abdominal distention; diarrhoea; flatulence
- Hair loss; itching
- Headache; dizziness
- Tiredness; swelling in the hands or legs

**Uncommon side effects (affect up to 1 in 100 patients):**

- Nausea; vomiting
- Irritation or inflammation of the oesophagus or stomach
- Black or tarry stools
- Blurred vision; pain or redness in the eye
- Rash; redness of the skin
- Transient flu-like symptoms, such as muscle pain, generally feeling unwell, sometimes with fever, usually at the beginning of treatment
- Taste disturbances

**Rare side effects (affect up to 1 in 1,000 patients):**

- Symptoms of low blood calcium levels, including muscle cramps or spasms and/or tingling sensation in the fingers or around the mouth
- Gastric or peptic ulcers (sometimes severe or with bleeding)
- Oesophageal stricture
- Rash worsened by sunlight
- Mouth ulcers

**Very rare side effects (affect up to 1 in 10,000 patients):**

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

**If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.**

You can report side effects to the Ministry of Health by following the link "Reporting Side Effects of Drug Treatment" on the Ministry of Health home page ([www.health.gov.il](http://www.health.gov.il)) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

#### 5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

##### Storage conditions:

- Store below 30°C. Store in the original package to protect from moisture. Do not remove the soluble tablets from the strip until you are ready to take the medicine.
- Do not throw away any medicine via wastewater or household waste. Ask the pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

#### 6. Additional information

**In addition to the active ingredient, this medicine also contains:**

Monosodium citrate anhydrous, citric acid anhydrous, sodium hydrogen carbonate, sodium carbonate anhydrous, strawberry flavour (PHS-132962), acesulfame potassium, sucralose.

**What the medicine looks like and contents of the pack**  
A flat, round, white to off-white tablet with beveled edges. After the tablet is dissolved, a clear to slightly cloudy solution is obtained.

Each pack contains 4, 12 or 24 effervescent tablets in an aluminum blister.

Not all pack sizes may be marketed.

**Registration holder's name and address:** Tzamal Bio-Pharma Ltd., 20 Hamagshimim St., Petach Tikva.

**Manufacturer's name and address:** Swiss Co-Services AG, Sisseln, Switzerland.

Revised in July 2022 according to MOH guidelines.

**Registration number of the medicine in the National Drug Registry of the Ministry of Health:** 158-96-34539