

Medication Guide
BINOSTO™ (BIN-oss-tow)
(alendronate sodium)
Effervescent Tablets

Read the Medication Guide that comes with BINOSTO™ before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking with your doctor about your medical condition or treatment.

What is the most important information I should know about BINOSTO Effervescent Tablet?

BINOSTO Effervescent Tablet can cause serious side effects, including:

1. Esophagus problems
2. Low calcium levels in your blood (hypocalcemia)
3. Bone, joint, or muscle pain
4. Severe jaw bone problems (osteonecrosis)
5. Unusual thigh bone fractures

1. Esophagus problems.

Some people who take BINOSTO may develop problems in the esophagus (the tube that connects the mouth and the stomach). These problems include irritation, inflammation, or ulcers of the esophagus which may sometimes bleed.

- **It is important that you take BINOSTO exactly as prescribed to help lower your chance of getting esophagus problems. (See the section “How should I take BINOSTO?”)**
- **Stop taking BINOSTO and call your doctor right away if you get chest pain, new or worsening heartburn, or have trouble or pain when you swallow.**

2. Low calcium levels in your blood (hypocalcemia).

BINOSTO may lower the calcium levels in your blood. If you have low blood calcium before you start taking BINOSTO, it may get worse during treatment. Your low blood calcium must be treated before you take BINOSTO. Most people with low blood calcium levels do not have symptoms, but some people may have symptoms. Call your doctor right away if you have symptoms of low blood calcium such as:

- Spasms, twitches, or cramps in your muscles
- Numbness or tingling in your fingers, toes, or around your mouth

Your doctor may prescribe calcium and vitamin D to help prevent low calcium levels in your blood, while you take BINOSTO. Take calcium and vitamin D as your doctor tells you to.

3. Bone, joint, or muscle pain.

Some people who take BINOSTO develop severe bone, joint, or muscle pain.

4. Severe jaw bone problems (osteonecrosis).

Severe jaw bone problems may happen when you take BINOSTO. Your doctor should examine your mouth before you start BINOSTO. Your doctor may tell you to see your dentist before you start BINOSTO. It is important for you to practice good mouth care during treatment with BINOSTO.

5. Unusual thigh bone fractures.

Some people have developed unusual fractures in their thigh bone. Symptoms of a fracture may include new or unusual pain in your hip, groin, or thigh.

Call your doctor right away if you have any of these side effects.

What is BINOSTO Effervescent Tablet?

BINOSTO is a prescription medicine used to:

- Treat thinning of your bones (osteoporosis) in women after menopause. BINOSTO helps reduce the chance of having a hip or spinal fracture (break).
- Increase bone mass in men who have osteoporosis.

It is not known how long BINOSTO works for the treatment of osteoporosis. You should see your doctor regularly to determine if BINOSTO is still right for you.

BINOSTO is not for use in children.

Who should not take BINOSTO Effervescent Tablet?

Do not take BINOSTO if you:

- Have certain problems with your esophagus, the tube that connects your mouth with your stomach
- Cannot stand or sit upright for at least 30 minutes
- Have trouble swallowing liquids
- Have low levels of calcium in your blood
- Are allergic to BINOSTO or any of its ingredients. See the end of this leaflet for a complete list of ingredients in BINOSTO.

What should I tell my doctor before taking BINOSTO Effervescent Tablet?

Before you start taking BINOSTO, tell your doctor about all of your medical conditions, including if you:

- Have problems with swallowing
- Have stomach or digestive problems
- Have low blood calcium
- Plan to have dental surgery or teeth removed
- Have kidney problems
- Have been told you have trouble absorbing minerals in your stomach or intestines (malabsorption syndrome)
- Have been told to lower your salt intake
- Are pregnant or planning to become pregnant. It is not known if BINOSTO can harm your unborn baby.
- Are breastfeeding or plan to breastfeed. It is not known if BINOSTO passes into your milk and may harm your baby.

Tell your doctor about all medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Especially tell your doctor if you take:

- calcium
- antacids
- aspirin
- Nonsteroidal Anti-Inflammatory (NSAID) medicines

Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist each time you get a new medicine.

How should I take BINOSTO Effervescent Tablet?

- Take BINOSTO exactly as your doctor tells you.
- BINOSTO is taken 1 time each week. Choose the day of the week that best fits your schedule, then take BINOSTO on the same day every week.
- **BINOSTO works only if you take it on an empty stomach.**
- Take BINOSTO **after** you get up for the day and **30 minutes before** taking your first food, drink, or other medicine.
- Take BINOSTO while you are sitting or standing.
- **Do not swallow, chew or suck on a BINOSTO tablet.**
- **Do not dissolve BINOSTO in:**
 - mineral or flavored water
 - coffee
 - tea
 - soda
 - juice

- **You must dissolve your BINOSTO effervescent tablet in plain water at room temperature before you take it. To prepare your BINOSTO liquid medicine:**

Step 1. Place the BINOSTO tablet in about a half glass (4 ounces) of plain water. The water should **not** be cold or hot, and should be at room temperature.

Step 2. Wait at least 5 minutes after the bubbling (effervescence) stops for the BINOSTO tablet to completely dissolve in the water.

Step 3. Stir the liquid medicine for about 10 seconds.

Step 4. Drink all of the BINOSTO liquid medicine in the glass.

After you take BINOSTO, wait at least 30 minutes before you:

- lie down. You may sit, stand or walk, and do normal activities like reading.
- take your first food or drink, except for plain water.
- take other medicines, including antacids, calcium, and other supplements and vitamins.

Do not lie down until after you eat your first food of the day.

- If you miss a dose of BINOSTO, do not take it later in the day. Take your missed dose on the next morning after you remember and then return to your normal schedule. Do not take 2 doses on the same day.
- If you think you took more than your prescribed dose of BINOSTO, drink a full glass of milk and call your doctor right away. Do not try to vomit. Do not lie down.

What should I avoid while taking BINOSTO Effervescent Tablet?

BINOSTO contains a high amount of salt in each tablet. Avoid eating foods with a high amount of salt if your doctor has told you to limit how much salt you eat.

What are the possible side effects of BINOSTO Effervescent Tablet?

BINOSTO may cause serious side effects.

- See **"What is the most important information I should know about BINOSTO?"**

The most common side effects of BINOSTO are:

- Stomach area (abdominal) pain
- Heartburn
- Constipation
- Diarrhea
- Upset stomach
- Pain in your bones, joints, or muscles
- Nausea

You may get allergic reactions, such as hives or, in rare cases, swelling of your face, lips, tongue, or throat.

Tell your doctor about any side effect that bothers you or that does not go away.

These are not all the side effects with BINOSTO. Ask your doctor or pharmacist for more information.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store BINOSTO Effervescent Tablet?

- Store BINOSTO at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep BINOSTO tablets in their original blister pack until you use them.
- Protect BINOSTO from moisture.

Keep BINOSTO and all medicines out of the reach of children.

General information about the safe and effective use of BINOSTO Effervescent Tablet

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use BINOSTO for a condition for which it was not prescribed. Do not give BINOSTO to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about BINOSTO. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about BINOSTO that is written for health professionals.

For more information, go to www.BINOSTO.com, or call 1-855-778-0177.

What are the ingredients in BINOSTO Effervescent Tablet?

Active ingredient: alendronate sodium

Inactive ingredients: monosodium citrate anhydrous, citric acid anhydrous, sodium hydrogen carbonate, sodium carbonate anhydrous, strawberry flavor, acesulfame potassium, and sucralose.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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