LBL107

Medication Guide

Alendronate Sodium Tablets, USP

Read the Medication Guide that comes with Alendronate Sodium Tablets 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. Talk to your doctor if you have any questions about Alendronate Sodium Tablets.

What is the most important information I should know about alendronate sodium tablets?

Alendronate sodium tablets 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 alendronate sodium tablets 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 alendronate sodium tablets exactly as prescribed to help lower your chance of getting esophagus problems. (See the section "How should I take alendronate sodium tablets?")**
- **Stop taking alendronate sodium tablets 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).

Alendronate sodium tablets may lower the calcium levels in your blood. If you have low blood calcium before you start taking alendronate sodium tablets, it may get worse during treatment. Your low blood calcium must be treated before you take alendronate sodium tablets. 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 alendronate sodium tablets. Take calcium and vitamin D as your doctor tells you to.

3. Bone, joint, or muscle pain.

Some people who take alendronate sodium tablets develop severe bone, joint, or muscle pain.

4. Severe jaw bone problems (osteonecrosis).

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

5. Unusual thigh bone fractures.

Some people have developed unusual frae tures 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 alendronate sodium tablet?

Alendronate sodium tablet is a prescription medicine used to:

- Treat or prevent osteoporosis in women after menopause. It helps reduce the chance of having a hip or spinal fracture (break).
- Increase bone mass in men with osteoporosis.
- Treat osteoporosis in either men or women who are taking corticosteroid medicines.
- Treat certain men and women who have Paget's disease of the bone.

It is not known how long alendronate sodium tablet works for the treatment and prevention of osteoporosis. You should see your doctor regularly to determine if alendronte sodium tablet is still right for you. Alendronate sodium tablet is not for use in children.

Who should not take alendronate sodium tablets?

Do not take alendronate sodium tablets 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 low levels of calcium in your blood
- Are allergic to alendronate sodium tablet or any of its ingredients. A list of ingredients is at the end of this leaflet.

What should I tell my doctor before taking alendronate sodium tablets?

Before you start alendronate sodium tablets, be sure to talk to your doctor 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)
- Are pregnant, or plan to become pregnant. It is not known if alendronate sodium tablets can harm your unborn baby.
- Are breast-feeding or plan to breast-feed. It is not known if alendronate sodium

passes into your milk and may harm your baby.

Especially tell your doctor if you take:

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

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Certain medicines may affect how alendronate sodium tablet works.

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 alendronate sodium tablets?

- Take alendronate sodium tablets exactly as your doctor tells you.
- **Alendronate sodium tablet works only if taken on an empty stomach.**
- Take alendronate sodium tablets, **after** you get up for the day and **before** taking your first food, drink, or other medicine.
- Take alendronate sodium tablets while you are sitting or standing.
- **Do not chew or suck on a tablet of alendronate sodium.**
- Swallow alendronate sodium tablet with a full glass (6-8 oz) of plain water only.
- **Do not** take alendronate sodium tablets with mineral water, coffee, tea, soda, or juice.
- If you take **Alendronate Sodium Tablets Daily:**
  - Take 1 alendronate sodium tablet one time a day, every day **after** you get up for the day and **before** taking your first food, drink, or other medicine.
- If you take **Once Weekly Alendronate Sodium Tablets**:
  - Choose the day of the week that best fits your schedule.
  - Take 1 dose of alendronate sodium tablets every week on your chosen day **after** you get up for the day and **before** taking your first food, drink, or other medicine.

After swallowing alendronate sodium tablet, wait at least 30 minutes:

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

Do not lie down for at least 30 minutes after you take alendronate sodium tablets and after you eat your first food of the day.

If you miss a dose of alendronate sodium tablets, 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 take too much alendronate sodium tablets, call your doctor. Do not try to vomit. Do not lie down.

What are the possible side effects of alendronate sodium tablets?

Alendronate sodium tablets may cause serious side effects.

- See "**What is the most important information I should know about alendronate sodium tablets?**"

The most common side effects of alendronate sodium tablets 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 swelling of your face, lips, tongue, or throat.

Worsening of asthma has been reported.

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

These are not all the possible side effects of alendronate sodium tablets. For more information, ask your doctor or pharmacist.

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

How do I store alendronate sodium tablets?

- Store at 20° - 25°C (68° - 77°F); excursions permitted to 15° - 30°C (59° - 86°F) [see USP controlled Room Temperature].
- Keep alendronate sodium tablets in a tightly closed container.

Keep alendronate sodium tablets and all medicines out of the reach of children.

General information about the safe and effective use of alendronate sodium tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use alendronate sodium tablets for a condition for which it was not prescribed. Do not give alendronate sodium tablets 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 alendronate sodium tablets. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about alendronate sodium tablets that is written for health professionals.

For more information, call 1-888-848-3593.

What are the ingredients in alendronate sodium tablets?

Active ingredient: alendronate sodium

Inactive ingredients: microcrystalline cellulose, croscarmellose sodium, and magnesium stearate.

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Manufactured by:
AustarPharma LLC
Edison, NJ 08837, USA

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Virtus Pharmaceuticals LLC
Tampa, FL 33619
1-888-848-3593

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