

Tablets  
**Alendronate**<sup>TM</sup>  
ONCE WEEKLY  
Sodium Alendronate BP  
Alendronic Acid...70MG



## Alendronate Tablets®

### COMPOSITION :

Alendronate Sodium

### Each tablet contains

Alendronic Acid.....70 mg

**(Alendronate)** is indicated for treatment and prevention of osteoporosis in postmenopausal women.

How to take  
Once Weekly  
**ALENDRONATE**  
(Refer enclosed leaflet)

### Description :

Alendronate Tablets is an oral aminobiphosphante which is used for the treatment of established osteoporosis in post-menopausal women and is also indicated for the treatment of Paget's disease of the bone. Bisphosphonates are synthetic analogs of pyrophosphate that bind to the hydroxyapatite found in bone.

Alendronate Tablets is chemically described as (4-amino-1-hydroxybutylidene) bisphosphonic acid monosodium salt trihydrate. The empirical formula of Alendronate Tablets is  $C_4H_{12}NNaO_7P_2 \cdot 3H_2O$  and its formula weight is 325.12. Alendronate sodium is a white, crystalline, nonhygroscopic powder. It is soluble in water, very slightly soluble in alcohol, and practically insoluble in chloroform.

### Why Purchase "Alendronate Tablets" From Us?

- \* We can supply medications as per the quantity needed by our customers
- \* All Our medicines are FDA approved
- \* Customized Packaging
- \* On-Time Delivery of Medicines
- \* Fair Pricing

### Dosage

Take this medication exactly as prescribed and continue taking it for as long as your doctor instructs. How much medicine you take and how often you take it depends on many factors, including the condition being treated and the age and weight of the patient. Carefully read the patient leaflet provided with this medicine. In case you missed a dose, take the next dose as soon as you remember. Or else if it's time for your next dose, skip the missed one and continue with regular schedule. Do not double dose.

### Precaution

Do not discontinue medicine until you have consulted your doctor. Also, make sure that you know how the medicine affects you. Store this medicine at room temperature, away from heat and light and keep away from reach of children.

### What is Alendronate ?

Alendronate comes in both tablet and liquid solution forms. Tablets are taken with a glass of water in the morning, before breakfast. The manufacturer also recommends drinking some water when the drug is taken in solution form. You aren't supposed to eat within 30 minutes of taking the drug. It is available only by prescription and should be taken only under a doctor's care. You should not take alendronate while pregnant.



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Doctors set the dosage level for each patient. Typically osteoporosis patients take 5 to 10 mg/day. 5 mg/day is often used to prevent osteoporosis. Paget's disease patients take a much higher dose - 40 mg/day.

Alkaline phosphatase is an enzyme that can be used as a biomarker in alendronate treatment. Along with blood levels of calcium and phosphorus, it is periodically measured in patients. Bone density is often measured to see if the drug is working as intended. Alendronate is not approved for pregnant women, and because the drug stays in the body for years, it is not often used if there is a chance the patient may get pregnant in the future.

Because of the drug's impact on the bone system, patients often are advised to take calcium and Vitamin D supplements. Women over age 50 should consume 1200-1500 mg/day of elemental calcium and 800-1000 int. units/day of vitamin D.

It is commonly thought that osteoporosis results only from a reduction in bone mass (i.e., from bone loss). However, the condition can also result from never having obtained adequate bone mass during a person's adolescent and young adult years. Therefore, the risk factors for osteoporosis begin early in life and include genetic, clinical, medical, behavioral, and dietary vulnerabilities. Additionally, risk factors that occur in combinations augment the chance of osteoporosis in an additive fashion. In other words, someone with two risk factors has a higher risk than someone with just one risk factor.

Genetic risk factors include: Caucasian or Asian ethnicity, family history of fractures, and family history of osteoporosis. African Americans have the lowest occurrence of osteoporosis of all ethnic populations. Clinical risk factors for osteoporosis include: female gender, older age, estrogen deficiency, and low weight or small body size. Medical risk factors include: anorexia nervosa, hypogonadism, gastrointestinal disorders, malabsorption syndromes, hematologic disorders, and use of certain medications (e.g., glucocorticoids, diuretics, anticonvulsants, immunosuppressive medications, asthma medications, and some antibiotics). Behavioral and dietary risk factors include: excessive or too little exercise, smoking, high caffeine intake, consuming too much alcohol, and calcium and Vitamin D deficiencies.

### Side effects of Alendronate ?

The worst side effect of osteonecrosis of the jaw (ONJ), which is rare. ONJ is a side effect of bisphosphonates in general, not just alendronate. There were many lawsuits against Merck alleging ONJ injuries from people who took alendronate when Merck had the patent on it. A 2008 paper in the Journal of the American Dental Association cast doubts on the alendronate-ONJ connection. The author found that people who took bisphosphonates intravenously had a higher risk of ONJ, but people who took them orally, as most do, had a lower risk. This was based on review of 700,000 medical cases.

Osteonecrosis of the jaw has been recognized for over a century. Indeed, there was an epidemic of Phossy Jaw in the second half of the Nineteenth Century. Even at the time public health practitioners recognized the connection between yellow phosphorus (P4O10) workplace exposure phossy jaw. Hence the name Phossy Jaw.

That epidemic of Phossy Jaw notably affected people who worked in match factories. Matches of the day used yellow phosphorus. It is believed that when the phosphorus oxide gets in the body, it reacts with amino acids and water and carbon dioxide to produce alendronate and other bisphosphonates.



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(Contrary to urban legend, no connection has been found between consumption of cola drinks - which contain phosphoric acid - and phossy jaw.)

### Other possible side effects

Bone/joint/muscle pain. Somewhat related to ONJ, severe bone and joint has been reported during bisphosphonate treatment. Pain might show up immediately after the medicine is started or in several months later. Doctors have a range of options for dealing with osteoporosis, so be sure to speak up about any pain you experience.

**Esophagitis, dysphagia, esophageal ulcers, esophageal erosions, and esophageal stricture** have been reported with oral bisphosphonates.

**Ocular side effects** has been reported in a few cases.

Hypocalcemia - low calcium level in the blood. Your doctor may have a work-around or put you on a different type of medicine. Slightly lower calcium levels due to alendronate usually poses no problem, but patients who are vitamin D-deficient can get hypocalcemia. Patients taking alendronate should receive at least 1000 mg of elemental calcium and 800 IU of vitamin D per day unless they have hypercalcemia.

Intravenous administration can make the patient feel like he/she has the flu and develop a fever. The white blood cell count may be diminished. This usually passes in a few days.

Some people get stomach cramps or other gastrointestinal problems (gastrointestinal mucosa irritation) on alendronate. While gastrointestinal problems are side effects of many drugs, with some medicines you can reduce these effects by taking the drug with a meal. Unfortunately, absorption of alendronate is poorer with food - this is one reason you shouldn't eat or drink anything for at least 30 minutes after taking the medicine.

Paget's disease patients taking 40 mg/day are more apt to get gastrointestinal problems than osteoporosis patients who take one pill per week.

### Treatment with Alendronate

Alendronate comes as a tablet and a solution (liquid) to take by mouth. The solution is usually taken on an empty stomach once a week in the morning. The 5-mg and 10-mg tablets are usually taken on an empty stomach once a day in the morning, and the 30-mg and 70-mg tablets are usually taken on an empty stomach once a week in the morning. The 40-mg tablets are usually taken once a day in the morning for six months to treat Paget's disease of bone. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take alendronate exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Alendronate may not work properly and may damage the esophagus (tube between the mouth and stomach) or cause sores in the mouth if it is not taken according to the recommended instructions.

Alendronate has also been tried for treatment of anorexics, who often have skeletal problems due to malnutrition. However, tests have not been good and alendronate is not widely used for anorexics.



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A report in the Journal of Clinical Oncology in 2008 stated that alendronate improves bone density in men having androgen-deprivation therapy for prostate cancer. This was found through the results of a double-blind study. The study authors recommend doctors consider once-a-week alendronate for such patients.

A large study published in 2006 suggested that some women may be able to quit taking alendronate after 5 years without increasing bone fracture risk for another 5 years, but this mode of treatment is not widely used. Some doctors feel the medicine

should be stopped because of diminishing returns and because of the possibility (not definitively proven) that the medicine actually causes too much suppression of bone turnover, resulting in bones that become brittle along with increase density.

Recent systematic reviews have continued to show that alendronate reduces the risk of bone fractures. These studies followed women who took the drug for up to four years.

Interestingly, many doctors recommend against monitoring bone marrow density in patients on bisphosphonates, at least during the first three years. The results are thought to be of little value in determining whether to continue bisphosphonate administration. The density often continues to decline after the drug is started (even if the drug is working) and the accuracy of the density tests is not good enough.

### Precautions

Kids don't take this drug (their bones are still growing) and pregnant women don't take it. Alendronate has side effects, but overall it is well tolerated.

### Elimination

Alendronate is not metabolized by the body and stays in the bones for years. While it might not be absorbed in the intestine and eliminate through the feces, alendronate that does enter the bloodstream has a half-life in the body of over 10 years. It is not easily flushed out.

### Prevention of Osteoporosis

Prevention of osteoporosis can often be achieved by targeting those risk factors that a person has the ability to modify. The best-known method of preventing osteoporosis is to consume the recommended daily levels of Calcium and Vitamin D, as these two minerals are vital for bone growth and maintenance. Adolescents up to age 19 require 1,300 mg of Calcium each day, adults under age 50 need 1,000 mg of Calcium daily, and adults age 50 and over need 1,200 mg of daily Calcium. Adolescents and adults up to age 50 require 200 IU of daily Vitamin D, adults between age 50 and 70 require 400 IU of Vitamin D each day, and adults 71 years old and over require 600 IU daily. Achieving the recommended levels of Vitamin D and Calcium may require taking supplements, especially if someone is home-bound, lives in a climate with little sun exposure, or is taking medications that interfere with the body's ability to absorb calcium.



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Other effective methods of preventing the onset of osteoporosis include abstaining from smoking, getting sufficient exercise without over-exerting yourself, and limiting alcohol and caffeine intake. Persons that are already smokers may be able reduce their risk of osteoporosis to the level of never-smokers by quitting smoking. In women with estrogen deficiencies, mostly due to menopause, hormone replacement therapy (HRT) is approved by the FDA for osteoporosis prevention. However, due to the numerous health risks of HRT, taking HRT only for the prevention of osteoporosis is not recommended.

The American College of Physicians released guidelines in 2008, recommending doctors offer medicine to patients with osteoporosis and consider medicine for patients at risk for the disease. The report noted that bisphosphonates are effective for treatment and prevention, but that there is not actionable information on how long people should take them.

Doctors sometimes prescribe 5 mg/day or alendronate for patients they feel are at risk for osteoporosis.

