

PACKAGE LEAFLET: INFORMATION FOR THE USER

Alendronic Acid 10 mg Tablets

(Alendronic Acid)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Alendronic Acid Tablets is and what it is used for
2. Before you take Alendronic Acid Tablets
3. How to take Alendronic Acid Tablets
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1. What Alendronic Acid Tablets is and what it is used for

Alendronic Acid belongs to a group of non-hormonal medicines called bisphosphonates. Alendronic Acid prevents the loss of bone that occurs in men, post-menopausal women and patients receiving glucocorticoids such as prednisolone and methylprednisolone. Alendronic Acid also has been shown to help rebuild bone and makes bone less likely to fracture in post-menopausal women and men with osteoporosis.

What is Alendronic Acid Tablets used for

Your doctor has prescribed alendronic acid because you either have osteoporosis or you are at risk of developing this disease. Osteoporosis is a thinning and weakening of the bones. It is common in women after the menopause. The menopause occurs when the ovaries stop producing the female hormone, oestrogen or they are removed. Oestrogen helps to keep a woman's skeleton healthy. Following the menopause, bone loss occurs and bones become weaker. The earlier a woman reaches the menopause, the greater the risk of osteoporosis. Osteoporosis can also occur in men due to a number of causes including ageing and/or a low level of the male hormone, testosterone. In all instances, bone is removed faster than it is formed, so bone loss occurs and bones become weaker. A class of steroid hormones (Corticosteroids) can also cause bone loss and osteoporosis in both sexes.

Early on, osteoporosis usually has no symptoms. If left untreated, however, it can result in fractures (broken bones). Although fractures usually cause pain, fractures of the bones of the spine may go unnoticed until they cause height loss. Fractures (broken bones) may occur during normal, everyday activity, such as lifting, or from minor injury that would not be sufficient to fracture normal bone. Fractures (broken bones) usually occur at the hip, spine, or wrist and can lead not only to pain but also to considerable deformity (problem) and disability (such as stooped posture, or 'dowager's hump', and loss of mobility).

How can osteoporosis be treated/prevented?

It is important to remember that if you already have osteoporosis that it can be treated and that it is never too late to begin. Your doctor has prescribed these tablets to treat your osteoporosis or to prevent you from developing this disease. Alendronic acid not only prevents the loss of bone but actually helps to rebuild bone you may have lost and make bone less likely to fracture. In addition to your treatment with alendronic acid, your doctor may recommend that you make some changes to your lifestyle, which may help your condition. These are:

- Stopping smoking:* Smoking appears to increase the rate at which you lose bone and, therefore, may increase your risk of fracture.
- 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.

2. Before you take Alendronic Acid Tablets

Do not take Alendronic Acid Tablets

- If you have certain disorders of the oesophagus (sometimes called the gullet and is the tube that connects your mouth with your stomach) such as narrowing or difficulty swallowing
- If you are unable to stand or sit upright for at least 30 minutes
- If you are allergic (hypersensitive) to alendronic acid or any of the other ingredients of alendronic acid
- 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 tablets. Talk to your doctor first and follow his advice.

Take special care with Alendronic Acid Tablets

It is important to tell your doctor before taking Alendronic Acid Tablets

- If you suffer from kidney problems
- If you have any allergies
- If you have any swallowing or digestive problems
- If your doctor has told you that you have Barrett's oesophagus (a condition associated with changes in the cells that line the lower oesophagus)
- If you have low blood calcium
- If you have gum disease
- If you have a planned dental extraction

A dental examination should be considered before you start treatment with alendronic acid tablets if you have any of the conditions below.

- You have cancer
- You don't receive routine dental care
- You are undergoing chemotherapy or radiotherapy
- You are taking steroids
- You have gum disease
- You are or have been a smoker (as this may increase the risk of dental problems)

Appropriate preventative dental care, as recommended by the dentist, should be followed during treatment.

It is important to maintain good oral hygiene when being treated with Alendronic acid tablets. 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 drink a full glass of water and/or if they lie down less than 30 minutes after taking alendronic acid tablets. These side effects may worsen if patients continue to take alendronic acid tablets after developing these symptoms.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

This medicine can interact with other medication (e.g. non-steroidal anti-inflammatory medicines (NSAIDs) like aspirin, ibuprofen or naproxen) which you take by mouth, and it is important that you follow the advice given under the heading 'How to take Alendronic Acid Tablets'.

Taking Alendronic Acid Tablets with food and drink

This medicine can interact with food and drink (e.g. mineral water, coffee, or tea, milk or juice), calcium supplements and antacids. It is important that you follow the advice given in 'How to take Alendronic Acid Tablets'

Children and adolescents

Alendronic acid Tablets should not be given to children and adolescents.

Pregnancy and breast-feeding

Alendronic acid tablet is only intended for use in postmenopausal women. You should not take alendronic acid tablets if you are or think you may be pregnant, or if you are breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine

Driving and using machines

There have been side effects (including blurred vision, dizziness and severe bone, muscle or joint pain) reported with alendronic acid tablets that may affect your ability to drive or operate machinery. Individual responses to alendronic acid tablets may vary (See POSSIBLE SIDE EFFECTS.)

Important information about some of the ingredients of Alendronic Acid Tablets

Alendronic Acid Tablets contains 0.039 g of lactose. When taken according to the dosage recommendations each dose supplies up to 0.039 g of lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicinal product.

3. How to take Alendronic Acid Tablets

Always take alendronic acid tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

You should do the following to help make sure you will benefit from alendronic acid tablets. *It is very important that you follow actions 1, 2, 3 and 4 to help the tablet reach your stomach quickly and help reduce potential for irritation of your oesophagus (the tube that connects your mouth with your stomach).*

1. After getting up for the day, and before taking any food, drink or other medicines, swallow your alendronic acid tablets with a full glass of plain water only (not less than 200 ml or 7 fluid ounce).
 - Do not take with mineral water

- Do not take with coffee or tea
 - Do not take with juice or milk
 - Do not crush or chew the tablet or allow it to dissolve in your mouth.
2. After swallowing your alendronic acid tablets do not lie down - stay fully upright (sitting or standing) for at least 30 minutes and until after your first food of the day. Do not chew or allow the tablet to dissolve in your mouth.
 3. Do not take alendronic acid tablets at bedtime or before getting up for the day.
 4. If you develop difficulty or pain upon swallowing, chest pain, or new or worsening heartburn, stop taking alendronic acid tablets and contact your doctor.
 5. After swallowing your tablet, wait at least 30 minutes before taking your first food, beverage, or other medication of the day, including antacids, calcium supplements and vitamins. Alendronic Acid Tablets is effective only if taken when your stomach is empty.
 6. You must take alendronic acid tablets exactly as your doctor has told you. It is important that you continue taking alendronic acid tablets for as long as your doctor prescribes the medicine. How much alendronic acid tablets you need to take will depend on why you are taking it and what other drugs you are taking.

Treatment of male osteoporosis or post-menopausal osteoporosis: The usual dose is one 'alendronic acid' 10 mg tablet once a day.

Prevention of steroid induced osteoporosis in post-menopausal women not receiving hormone replacement therapy (HRT) with an oestrogen: The usual dose is 10 mg once a day.

If you take more Alendronic Acid Tablets than you should

If you take too many tablets by mistake, drink a full glass of milk and contact your doctor immediately. Do not make yourself vomit, and do not lie down.

If you forget to take Alendronic Acid Tablets

If you miss a dose, do not take an extra tablet to make up, just carry on with the next dose as normal.

If you stop taking Alendronic Acid Tablets

It is important that you continue taking alendronic acid tablets for as long as your doctor prescribes the medicine. Alendronic Acid Tablets can treat your osteoporosis only if you continue to take the tablets.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, alendronic acid tablets can cause side effects, although not everybody gets them.

Most patients do not have side effects from taking these tablets; however, as with any medicine, they may have unintended or undesirable effects.

The following terms are used to describe how often side effects have been reported.

Very Common side effects (equal or more than 1 out of 10 patients)
 Common side effects (less than 1 out of 10 but more than 1 out of 100 people),
 Uncommon side effects (less than 1 out of 100 but equal or more than 1 out of 1,000 patients),
 Rare side effects (less than 1 out of 1000 but equal or more than 1 out of 10,000 patients),
 Very rare side effects (less than 1 out of 10,000 patients)

Common side effects (less than 1 out of 10 but more than 1 out of 100 people):

- heartburn;
- difficulty swallowing;
- pain upon swallowing;
- ulceration or perforation of the gullet (oesophagus - the tube that connects your mouth with your stomach) which can cause chest pain, heartburn or difficulty or pain upon swallowing and scarring, leading to narrowing of the oesophagus;
- bone, muscle and/or joint pain
- abdominal pain;
- uncomfortable feeling in the stomach or belching after eating;
- constipation;
- full or bloated feeling in the stomach;
- diarrhoea;
- flatulence;
- headache

Uncommon side effects less than 1 out of 100 but equal or more than 1 out of 1,000 patients):

- nausea;
- vomiting
- irritation or inflammation of the gullet (oesophagus - the tube that connects your mouth with your stomach) or stomach
- black or tar-like stools
- rash;
- itching;
- redness of the skin

Rare side effects (less than 1 out of 1000 but equal or more than 1 out of 10,000 patients):

- allergic reactions such as hives; swelling of the face, lips, tongue and/or throat, possibly causing difficulty breathing or swallowing
- symptoms of low blood calcium levels including muscle cramps or spasms and/or tingling sensation in the fingers or around the mouth
- stomach or peptic ulcers (sometimes severe or with bleeding)
- narrowing of the gullet (oesophagus – the tube that connects your mouth with your stomach)
- jaw problems associated with delayed healing and infection, often following tooth extraction
- blurred vision, pain or redness in the eye
- rash made worse by sunlight
- severe bone, muscle and/or joint pain
- mouth ulcers when the tablets have been chewed or sucked
- transient flu-like symptoms, such as aching muscles, generally feeling unwell and sometimes with fever usually at the start of treatment

Very rare side effects (less than 1 out of 10,000 patients):

- severe skin reactions

During post-marketing experience the following side effects have been reported (frequency unknown):

- dizziness,
- changed sense of taste,
- hair loss,
- joint swelling,
- tiredness,
- swelling in the hands or legs,
- fracture of the thigh bone in patients on long-term treatment with alendronic acid tablets. Thigh pain, weakness or discomfort may be an early indication of a possible fracture of the thigh bone.

Laboratory test findings:

- Very common: mild and transient decreases in blood calcium and phosphate levels, generally within the normal range.

Tell your doctor or pharmacist promptly about these or any other unusual symptoms. It will help if you make a note of what you experienced, when it started and how long it lasted.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Alendronic Acid Tablets

- Keep out of reach and sight of children.
- Do not use alendronic acid tablets after the expiry date, which is stated on the carton and blister after 'EXP'. The expiry date refers to the last day of that month.
- This medicinal product does not require any special storage conditions
- Medicine should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Alendronic Acid Tablets contains:

The active substance is alendronic acid (as sodium alendronate).

Each tablet contains 10mg alendronic acid (as alendronate sodium)

The other ingredients are lactose anhydrous, cellulose microcrystalline (E460), croscarmellose sodium and magnesium stearate.

What Alendronic Acid Tablets looks like and content of the pack:

Alendronic Acid 10 mg Tablets are available as white to off-white, oval, biconvex tablet, debossed with '10' on one side and plain on other side.

Alendronic Acid 10 mg Tablets are available in opaque white PVC/ALU blister packs containing 14, 28, 30, 50, 56, 84, 90, 98, 112* or 140* tablets.

*Not for UK market

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer :

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