PACKAGE LEAFLET

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 because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs and illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- It is particularly important to understand the information in section 3 How to take Alendronic acid, before taking this medicine.

What is in this leaflet

1. What Alendronic Acid Tablets are and what they are used for
2. What you need to know before you take Alendronic Acid Tablets
3. How to take Alendronic Acid Tablets
4. Possible side effects
5. How to store Alendronic Acid Tablets
6. Contents of the pack and other information

1. What Alendronic Acid Tablets are and what they are used for

What is Alendronic acid

Alendronic acid is a tablet containing the active substance alendronic acid (commonly called alendronate) and belongs to a group of medicines called bisphosphonates. Alendronic Acid prevents the loss of bone that occurs in women after they have been through the menopause. It can also prevent loss of bone in men or people taking steroids, such as prednisolone and methylprednisolone. It also has been shown to help rebuild bone and reduce the risk of spine and hip fractures (broken bones) in women (after their menopause) and in men who have thinning of their bones (osteoporosis).

What Alendronic Acid Tablets are used for

Your doctor has prescribed alendronic acid because you either have osteoporosis or you are at risk of developing this disease.

What is osteoporosis

Osteoporosis is a thinning and weakening of the bones. It is common in women after the menopause. At the menopause, the ovaries stop producing the female hormone, oestrogen, which helps to keep a woman's skeleton healthy. As a result, 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.

Corticosteroids can also cause bone loss and osteoporosis in both men and women.

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

How can osteoporosis be treated/prevented?

As well as 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 broken bones.
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 (especially calcium and vitamin D).

2. Before you take Alendronic Acid Tablets

Do not take Alendronic Acid Tablets if you:

- are allergic to alendronic acid, the active ingredient, or any of the other ingredients of this medicine (listed in section 6)
- 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
- cannot stand or sit upright for at least 30 minutes
- 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 the advice given.

Warnings and precautions
Talk to your doctor or pharmacist before taking Alendronic acid tablets.

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

- you suffer from kidney problems
- you have, or have recently had, any swallowing or digestive problems
- your doctor has told you that you have Barrett's oesophagus (a condition associated with changes in the cells that line the lower oesophagus)
- you have been told you have trouble absorbing minerals in your stomach or intestines (malabsorption syndrome)
- you have been told you have low blood calcium
- 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 in the treatment of cancer
- you are taking corticosteroids (such as prednisone or dexamethasone) which are used in the treatment of such conditions as asthma, rheumatoid arthritis, and severe allergies,

- you are or have been a smoker (as this may increase the risk of dental problems).

You may be advised to have a dental check-up before starting treatment with Alendronic acid.

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.

Children and adolescents
Alendronic acid tablets should not be given to children and adolescents less than 18 years of age.

Other medicines and Alendronic acid Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

It is likely that calcium supplements, antacids, and some oral medicines will interfere with the absorption of Alendronic acid tablets if taken at the same time. Therefore, it is important that you follow the advice given in section 3 How to take Alendronic acid Tablets.

Certain medicines for rheumatism or long-term pain called NSAIDs (e.g. acetylsalicylic acid (aspirin) or ibuprofen) might cause digestive problems. Therefore, caution should be used when these medicines are taken at the same time as Alendronic acid Tablets.

Alendronic Acid Tablets with food and drink

It is likely that food and drinks (including mineral water) will make Alendronic acid Tablets less effective if taken at the same time. Therefore it is important that you follow the advice given in Section 3 How to take Alendronic acid Tablets.

Pregnancy, breast-feeding and fertility

Alendronic acid tablet is only intended for use in postmenopausal women. You should not take alendronic acid tablets if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this 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 section 4.)

Alendronic Acid Tablets contains lactose

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

Alendronic Acid Tablets contains sodium
This medicinal product contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

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.

Taking your medicine

It is very important that you follow actions 1 to 5 help the tablet reach your stomach quickly and help reduce possible 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), so that alendronic acid tablets is adequately absorbed.
   − 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 crush or chew the tablet or allow it to dissolve in your mouth because of the possibility of mouth ulceration.
2. Do not lie down - stay fully upright (sitting, standing or walking) for at least 30 minutes after swallowing the tablet. Do not lie down until after your first food of the day.
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 talk to your doctor immediately.
5. After swallowing your tablet, wait at least 30 minutes before taking your first food, drink, or other medicine of the day, including antacids, calcium supplements and vitamins. Alendronic Acid Tablets will only work if your stomach is empty.

The recommended dose

- for the treatment of osteoporosis in men or post-menopausal women the recommended dose is 10 mg once a day.

- for the treatment and prevention of steroid induced osteoporosis in post-menopausal women not receiving hormone replacement therapy (HRT) with an oestrogen the recommended 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 forget to take your dose, skip the missed dose.
- Take the next dose as normal.
- Do not take a double dose to make up for a forgotten dose.

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. Since it is not known how long you should take Alendronic acid tablets, you should discuss the need to stay on this medicine with your doctor periodically to determine if Alendronic acid tablet is still right for you.

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

4. Possible side effects

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

See your doctor immediately if you notice any of the following side effects, which may be serious, and for which you may need urgent medical treatment:

Common (may affect up to 1 in 10 people):

- Heartburn; difficulty swallowing; pain upon swallowing; ulceration 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.

Rare (may affect up to 1 in 1,000 people):

- Allergic reactions such as hives; swelling of the face, lips, tongue and/or throat, possibly causing difficulty breathing or swallowing; severe reactions involving your skin, mucous membranes of your mouth, nose eyes or genitals. Stop taking this medicine and contact your doctor right away if you experience such symptoms;
- Pain in the mouth, and/or jaw, swelling or sores inside the mouth, numbness or a feeling of heaviness in the jaw, or loosening of a tooth. These could be signs of bone damage in the jaw (osteonecrosis) generally associated with delayed healing and infection, often following tooth extraction. Contact your doctor and dentist if you experience such symptoms;
- unusual fracture of the thigh bone particularly in patients on long-term treatment for osteoporosis may occur rarely. Contact your doctor if you experience pain, weakness or discomfort in your thigh, hip or groin as this may be an early indication of a possible fracture of the thigh bone;
- bone, muscle and/or joint pain which is severe.

Other side effects include:

Very common (may affect more than 1 in 10 people):

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

Common (may affect more than 1 in 10 people):

- joint swelling
- abdominal pain; uncomfortable feeling in the stomach or belching after eating; constipation; full or bloated feeling in the stomach; diarrhoea; flatulence;
- hair loss; itching;
- headache; dizziness;
- tiredness; swelling in the hands or legs.

Uncommon (may affect up to 1 in 100 people):

- 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
- blurred vision; pain or redness in the eye;
- rash; redness of the skin
- transient flu-like symptoms, such as aching muscles, generally feeling unwell and sometimes with fever usually at the start of treatment;
- taste disturbance.

Rare (may affect up to 1 in 1000 people):

- 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)
- rash made worse by sunlight
- mouth ulcers when the tablets have been chewed or sucked

Very rare (may affect up to 1 in 10,000 people):

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

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Alendronic Acid Tablets

- Keep this medicine out of the sight and reach 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
- Do not throw any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Alendronic Acid Tablets contain:

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 look 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

VAR/IA/033G/INI

Marketing Authorisation Holder

To be completed nationally

Manufacturer
Accord Healthcare Polska Sp.z o.o.,
ul. Lutomierska 50,95-200 Pabianice, Poland

Accord Healthcare single member S.A.,
64th Km National Road Athens, Lamia, Schimatari, 32009, Greece

This medicinal product is authorised in the Member States of the EEA under the following names:

Country		**Proposed Name**
Netherlands (THE)	:	Alendroninezuur Accord 10 mg tabletten
UK	:	Alendronic Acid 10 mg Tablets

This leaflet was last revised in
<To be completed nationally>