

Package leaflet: Information for the patient

Alendronic Acid Once Weekly 70 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. Do not pass it on to others. It may harm them, even if their signs of 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.

What is in this leaflet:

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

1. What Alendronic Acid Once Weekly is and what it is used for

Alendronate belongs to a group of non-hormonal medicines called bisphosphonates. Alendronate prevents the loss of bone that occurs in women after they have been through the menopause, and helps to rebuild bone. It reduces the risk of spine and hip fractures.

Your doctor has prescribed Alendronic Acid Once Weekly to treat your **osteoporosis**. Alendronic Acid Once Weekly has been shown to **reduce the risk of spine and hip fractures**.

Alendronic Acid Once Weekly is a **once weekly** treatment.

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.

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 injury that would not generally break normal bone. Broken bones usually occur at the hip, spine, or wrist and can lead not only to pain but also to considerable problems like stooped posture ('dowager's hump') and loss of mobility.

As well as your treatment with Alendronic Acid Once Weekly, your doctor may suggest you make changes to your lifestyle to help your condition, such as:

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.

2. What you need to know before you take Alendronic Acid Once Weekly

Do not take Alendronic Acid Once Weekly

- if you are allergic to alendronic acid or any of the other ingredients of this medicine (listed in section 6).
- if you have **certain problems with your gullet** (oesophagus - the tube that connects your mouth with your stomach) such as narrowing or difficulty swallowing
- if you **cannot stand or sit upright for at least 30 minutes**
- 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 the advice given.

Warnings and precautions

Tell your doctor before taking **Alendronic Acid Once Weekly**

- if you suffer from **kidney problems**
- 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 gullet).
- if you have **low blood calcium** levels
- if you have **gum disease, planned dental extraction, poor dental health or you don't receive routine dental care**
- if you have cancer
- if you are undergoing chemotherapy or radiotherapy
- if you are taking angiogenesis inhibitors (such as bevacizumab, or thalidomide)
- if you are taking corticosteroids (such as prednisone or dexamethasone)
- if you are or have been a smoker (as this may increase the risk of dental problems)

It is important to maintain good oral hygiene when being treated with **Alendronic Acid Once Weekly**.

You may be advised to have a dental check-up before starting treatment with **Alendronic Acid Once Weekly**.

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 Once Weekly. These side effects may worsen if patients continue to take Alendronic Acid Once Weekly after developing these symptoms.

Children and adolescents

Alendronic Acid Once Weekly should not be given to children and adolescents.

Other medicines and Alendronic Acid Once Weekly

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 Once Weekly if taken at the same time. Therefore, it is important that you follow the advice given in section 3. "How to take Alendronic Acid Once Weekly".

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

Alendronic Acid Once Weekly with food and drink

It is likely that food and beverages (including mineral water) will make Alendronic Acid Once Weekly 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 Once Weekly".

Pregnancy and breast-feeding

You should not take Alendronic Acid Once Weekly if you are or think you may be pregnant. Alendronic Acid Once Weekly is only intended for use in postmenopausal women.

You should not take Alendronic Acid Once Weekly if you are breast-feeding. Alendronic Acid Once Weekly is only intended for use in postmenopausal women.

Driving and using machines

Certain side effects (including blurred vision, dizziness and severe bone, muscle and/or joint pain) have been reported during treatment with alendronate which may impair your ability to drive or use machines. The reaction to alendronate may differ from individual to individual (see section 4).

Alendronic Acid Once Weekly contains lactose and sodium.

If you have been told by your doctor that you have an intolerance to some sugars (for example lactose), contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

3. How to take Alendronic Acid Once Weekly

Always take Alendronic Acid Once Weekly exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Take one 70 mg tablet once a week.

Follow these instructions carefully to make sure you will benefit from Alendronic Acid Once Weekly.

1) Choose the day of the week that best fits your schedule. Every week, take one Alendronate 70 mg tablet on your chosen day.

It is very important to follow instructions 2), 3), 4) and 5) to help the Alendronic Acid Once Weekly reach your stomach quickly and help reduce the chance of irritating your gullet (oesophagus - the tube that connects your mouth with your stomach).

2) After getting up for the day and before taking any food, drink, or other medicine, swallow your Alendronate 70 mg tablet whole **with a full glass of water** only (not mineral water) (not less than 200 ml or 7 fl. oz.).

- Do not take with mineral water (still or sparkling).
- Do not take with coffee or tea.
- Do not take with juice or milk.

3) Do not chew or crush the tablet or allow it to dissolve in your mouth.

4) 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.

5) Do not take Alendronic Acid Once Weekly at bedtime or before getting up for the day.

6) If you develop difficulty or pain upon swallowing, chest pain, or new or worsening heartburn, stop taking Alendronic Acid Once Weekly and contact your doctor.

7) After swallowing your Alendronic Acid Once Weekly, **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 Once Weekly is effective only if taken when your stomach is empty.

If you take more Alendronic Acid Once Weekly 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 Once Weekly

If you miss a dose, just take one tablet on the morning after you remember. Do not take two tablets on the same day. Return to taking one tablet once a week, as originally scheduled on your chosen day.

If you stop taking Alendronic Acid Once Weekly

It is important that you take Alendronic Acid Once Weekly for as long as your doctor prescribes the medicine. Since it is not known how long you should take Alendronic Acid Once Weekly, you should discuss the need to stay on this medicine with your doctor periodically to determine if Alendronic Acid Once Weekly 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 Once Weekly can have 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:

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

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

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 extensive skin damage (separation of the epidermis and superficial mucous membranes) - toxic epidermal necrolysis
- an extremely intense allergic reaction with skin rashes, commonly in the form of blisters or sores in the oral cavity and eyes, and other mucous membranes such as, for example, genitalia (Stevens-Johnson syndrome)
- 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 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. 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.

Other side effects that may occur:

Common (may affect up to 1 in 10 people)

- headache
- dizziness
- abdominal pain
- uncomfortable feeling in the stomach or belching after eating
- constipation
- full or bloated feeling in the stomach
- diarrhoea
- flatulence
- joint swelling
- hair loss; itching
- 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
- 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
- blurred vision; pain or redness in the eye.

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

- narrowing of the gullet (oesophagus - the tube that connects your mouth with your stomach)
- mouth ulcers when the tablets have been chewed or sucked
- stomach or peptic ulcers (sometimes severe or with bleeding)
- rash made worse by sunlight
- symptoms of low blood calcium levels including muscle cramps or spasms and/or tingling sensation in the fingers or around the mouth.

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.

It will help if you make a note of what you experienced, when it started and how long it lasted.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Alendronic Acid Once Weekly

Keep this medicine out of the sight and reach of children.

Do not use this medicine 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.

Do not store above 25°C. Store in the original package in order to protect from moisture.

Do not throw away 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 Once Weekly contains

The active substance is alendronic acid.

Each tablet contains 70 mg of alendronic acid (as alendronate sodium trihydrate).

The other ingredients are microcrystalline cellulose, lactose monohydrate, croscarmellose sodium and magnesium stearate.

What Alendronic Acid Once Weekly looks like and contents of the pack

Alendronic Acid Once Weekly is a white to off-white, oval tablet, embossed with “AN 70” on one side and the Arrow logo on the other.

The tablets are packed in Alu/PVC/PE/PVDC blisters which are inserted in a carton folder.

Pack sizes:

Blister: 2, 4, 8, 12, 24 or 40 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

Salutas Pharma GmbH, Otto-von-Guericke Allee 1, 39179 Barleben, Germany.

Arrow Generics Limited, Unit 2, Eastman Way, Stevenage, Hertfordshire SG1 4SZ, United Kingdom.

Qualiti (Burnley) Limited, Talbot Street, Briercliffe, Burnley BB102JY, United Kingdom.

Arrow Pharm Limited, HF 62, Hal Far Industrial Estate, Birzebbugia BBG06, Malta.

Actavis Ltd., BLB 016, Bulebel Industrial Estate, Zejtun ZTN 3000, Malta.

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

Belgium:	Alendronate Sandoz 70 mg tabletten Wekelijks
Czech Republic:	ALENDRONAT SANDOZ 70
France:	ACIDE ALENDRONIQUE SANDOZ 70 mg, comprimé
Germany:	Alendron-HEXAL® einmal wöchentlich 70 mg Tabletten
Greece:	FOROSA
Hungary:	Alendron-HEXAL 70 mg tablets
Ireland:	Alendronic Acid Once Weekly 70 mg Tablets
Italy:	ALENDRONATO SANDOZ 70 mg compresse
Luxembourg:	Alendronate Sandoz 70 mg comprimés Hebdomadaire
Portugal:	ÁCIDO ALENDRÓNICO Sandoz 70 mg COMPRIMIDOS
Spain:	Acido Alendronico Semanal Sandoz 70 mg comprimidos EFG

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