

**PACKAGE LEAFLET: INFORMATION FOR THE USER**

**Alendronic Acid 70mg 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 get 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 70mg Tablets are and what they are used for
2. Before you take Alendronic Acid 70mg Tablets
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**1. WHAT ALENDRONIC ACID 70MG TABLETS ARE AND WHAT THEY ARE USED FOR**

Alendronic acid belongs to a group of non-hormonal medicines known as bisphosphonates, which prevent bone loss from the body.

Alendronic acid is used to treat a condition called osteoporosis (brittle bones). This condition is common in women after the menopause. The earlier a woman reaches the menopause, the greater the risk of her developing osteoporosis.

Without treatment, osteoporosis can cause thinning and weakening of the bones in the skeleton which can then lead to fractures, usually of the hip, backbone and wrists. Fractures can occur easily in people suffering from osteoporosis including during normal everyday activities such as heavy lifting or from a minor injury or fall.

Alendronic acid helps to prevent bone loss and to build up bone which may have been lost due to osteoporosis. It can therefore reduce the risk of back and hip fractures.

**2. BEFORE YOU TAKE ALENDRONIC ACID 70MG TABLETS**

**Do not take Alendronic Acid 70mg Tablets:**

- If you are allergic (hypersensitive) to alendronic acid
- If you are allergic to any of the other ingredients in the tablets (these are listed in section 6, Further Information)
- If you have certain disorders of the oesophagus (this is also called the gullet and is the tube that connects your mouth with your stomach) such as narrowing of the gullet or difficulty swallowing
- If your doctor has told you that you have low calcium levels in your blood
- If you are unable to stand or sit upright for at least 30 minutes at a time.

**Take special care with Alendronic Acid 70mg Tablets:**

Tell your doctor before taking these tablets:

- If you have difficulty or pain when swallowing
- If you have inflammation of the stomach lining or the duodenum (first section of the small intestine)
- If you have a stomach ulcer or other digestive problems including bleeding in the stomach
- If you have had surgery on your stomach or gullet in the last year (not including pyloroplasty which is where the outlet from the stomach is widened)
- 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 or have ever had any kidney problems
- If you have or have ever had low vitamin D levels. If so your doctor may wish to monitor your vitamin D levels during treatment with alendronic acid
- If you have or have had a condition called hypoparathyroidism (a condition where your parathyroid gland does not work properly)
- If you have or have had pain, swelling or numbness of the jaw, loosening of a tooth or a 'heavy jaw feeling'
- If you are undergoing dental treatment or you are to undergo dental surgery
- If you have cancer, are undergoing chemotherapy or radiotherapy, are taking steroids, do not receive regular dental care, have a mouth infection or smoke. If so your doctor may want you to have a dental examination before starting treatment.

It is important to maintain good oral hygiene when being treated with Alendronic Acid 70mg 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.

**Taking other medicines**

Do not take any other medicines orally (by mouth) at the same time as taking Alendronic Acid 70mg Tablets. You should leave **at least 30 minutes** between your dose of Alendronic Acid 70mg Tablets and any other oral medicines. It is important that you follow all of the advice given in section 3 - 'How to take Alendronic Acid 70mg Tablets.'

You should speak to your Doctor before you take Alendronic Acid 70mg Tablets if you are currently taking a non-steroidal anti-inflammatory drug (NSAID).

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

**Taking Alendronic Acid 70mg Tablets with food and drink**

These tablets must be taken on an empty stomach as food and drink can greatly reduce the effectiveness of the medicine. You must take the tablets with a full glass of plain water **at least 30 minutes** before any other food or drink. It is important that you follow all of the advice given in section 3 - 'How to take Alendronic Acid 70mg Tablets.'

**Pregnancy and breast-feeding**

Do not take Alendronic Acid 70mg Tablets if you are pregnant, think you may be pregnant or are breast-feeding.

**Driving and using machines**

Alendronic Acid 70mg Tablets are not expected to have any effects on your ability to drive and use machines. However in rare cases patients taking Alendronic Acid 70mg Tablets can suffer from side effects including dizziness, severe muscle joint and bone pain and eye pain or inflammation. If you are affected in this way, you should contact your doctor before driving or using machinery.

**Important Information about some of the ingredients of Alendronic Acid 70mg Tablets**

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

**3. HOW TO TAKE ALENDRONIC ACID 70MG TABLETS**

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

Alendronic Acid 70mg Tablets must be taken **once a week**.

The following instructions are particularly important to ensure that your medicine is effective and to reduce the likelihood of the medicine irritating your oesophagus (gullet):

- Choose the day of the week that best suits you to take your tablet.
- Take one Alendronic Acid 70mg Tablet each week on your chosen day.
- Immediately after getting up on your chosen day, take the Alendronic Acid 70mg Tablet on an empty stomach. It should only be taken with a full glass of **plain water** (not less than 200ml) and should be taken **at least 30 minutes** before any other food, drink or medicine. Do not take your tablet with tea, coffee, mineral water or juice.
- The tablet must be swallowed whole. You must not chew or crush the tablet or allow it to dissolve in your mouth.
- Wait at least 30 minutes after taking the tablet before you drink or eat the first meal of the day or take any other medicine (this includes calcium supplements, vitamins and antacids (which are used to treat indigestion)).
- Do not lie down after taking Alendronic Acid 70mg Tablets. You must stay upright (sitting, standing or walking) for at least 30 minutes after you have swallowed the tablet. It is also important that you do not lie down before you have eaten the first meal of the day.
- Do not take your tablet at bedtime or before you get out of bed in the morning.
- If you find it difficult and/or painful to swallow, or you feel pain behind the breast-bone or new or worsened heartburn, stop taking the tablets and contact your doctor.

Your doctor may also ask you to take vitamin D or calcium supplements whilst you are taking Alendronic Acid 70mg Tablets. If so, you should follow your doctor's advice carefully.

It is important that you continue to take Alendronic Acid 70mg Tablets for as long as your doctor recommends. Alendronic Acid 70mg Tablets can only treat your osteoporosis effectively if you continue to take the tablets.

#### **Alendronate should not be given to children and adolescents.**

**If you take more Alendronic Acid 70mg Tablets than you should,** you may suffer from a stomach upset, heartburn, inflammation of the gullet or stomach, muscle and stomach cramps, spasms, weakness and fits. You should drink a full glass of milk and contact your nearest doctor or hospital casualty department immediately. Do not try and make yourself sick (vomit) and do not lie down.

**If you forget to take Alendronic Acid 70mg Tablets,** take one tablet on getting up the next morning after you remember.

**Do not take two tablets on the same day.** Return to taking one tablet once a week on the day that you originally decided upon.

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 70mg Tablets can cause side effects, although not everybody gets them.

**All medicines can cause allergic reactions, although serious allergic reactions are very rare. You should stop taking Alendronic Acid 70mg Tablets and tell your doctor immediately if you get any of the following symptoms:**

- sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body). This is known as 'angioedema'.
- a rash, blistering or other effects on the skin, eyes, mouth or genitals, itching or high temperature (symptoms of severe skin reactions called Stevens-Johnson syndrome or toxic epidermal necrolysis).

**If you have difficulty and/or pain when swallowing, you feel pain behind the breast-bone or new or worsened heartburn, stop taking Alendronic Acid 70mg Tablets and contact your doctor.** If you ignore these symptoms and continue to take your tablets it is likely that these gullet reactions may get worse.

The following side effects have been reported:

**Very common side effects** (probably affecting more than 1 in 10 people)

- Muscle, joint or bone pain, which is sometimes severe.

**Common side effects** (probably affecting less than 1 in 10 people):

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| • Stomach pain                           | • Constipation                                    | • Hair loss   |
| • Wind                                   | • Regurgitation of acid from the stomach (reflux) | • Itching (pruritus)  |
| • Vertigo                                | • Pain or difficulty when swallowing              | • Joint swelling  |
| • Indigestion                            | • Diarrhoea                                       | • Weakness or lack of energy  |
| • Full or bloated feeling in the stomach | • Headache  | • Excess fluid (swelling), usually in the legs (peripheral oedema). |
| • Ulceration of the oesophagus (gullet)  | • Dizziness                                       |   |

**Uncommon side effects** (probably affecting less than 1 in 100 people):

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| • Feeling and being sick (nausea and vomiting)         | • Reddening of the skin  |
| • Inflammation of the stomach                          | • Changes in your sense of taste   |
| • Inflammation and/or thinning (erosion) of the gullet | • Inflammation of the eye  |
| • Rash   | • Temporary flu-like symptoms (muscle pain, general feeling of illness and, in rare cases, fever) usually at the start of treatment. |
| • Black tarry stools                                   |  |

**Rare side effects** (probably affecting less than 1 in 1000 people):

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| • Narrowing of the gullet   | • Pain and/or inflammation of the jaw (this is more common in people who have had a tooth taken out and/or a mouth infection).  |
| • Allergic (hypersensitivity) reactions including swelling and skin eruptions   | • 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. |
| • Severe skin reactions (Stevens-Johnson syndrome and toxic epidermal necrolysis)                                       |   |
| • Stomach or other peptic ulcers (although it is not clear whether these ulcers are caused by alendronic acid)          |   |
| • Mouth and/or throat ulcers  |   |
| • Skin rash with sensitivity to light   |   |
| • Low calcium levels which may cause muscle cramps or spasms and tingling sensation in the fingers or around the mouth. |   |

**If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.** It will help if you make a note of what you experienced, when it started and how long it lasted.

#### **5. HOW TO STORE ALENDRONIC ACID 70MG TABLETS**

Keep out of the reach and sight of children.

Do not use your medicine after the expiry date which is stated on the carton after EXP:. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package.

Medicines 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 70mg Tablets contain:**

- The active substance is alendronic acid. Each tablet contains 70mg of alendronic acid as sodium alendronate trihydrate.
- The other ingredients are microcrystalline cellulose, lactose monohydrate, croscarmellose sodium and magnesium stearate.

**What Alendronic Acid 70mg Tablets look like and contents of the pack**

Alendronic Acid 70mg Tablets are white to off-white oval tablets stamped 'AN 70' on one side and '✓' on the other.

The tablets are available in blister packs of 2, 4, 8, 12 and 40 tablets. Not all pack sizes may be marketed.

**Marketing Authorisation Holder:**

Actavis Group PTC ehf, Reykjavíkurvegi 76-78, 220 Hafnarfjörður, Iceland

**Manufacturer:**

Arrow Pharm (Malta) Limited, HF 62, Hal Far Industrial Estate, Hal Far, BBG 3000, Malta.

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