

Artwork No.			Colours Used
Customer	Somex Pharma	■	Black
Description	Alendronic Acid Tablets_70 mg_Package leaflet		
Market	UK		
Language	English		
Size	138 x 275 mm		
Min. Font Size			
Version No.	03		
Pharma code			
Date	12.02.2024		
Software	Adobe Illustrator cs6		

## PACKAGE LEAFLET

### ALENDRONIC ACID 70 MG TABLETS

(Alendronate monosodium trihydrate)

#### 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 further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should 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 70 mg Tablets are and what they are used for
2. Before you take Alendronic Acid 70 mg Tablets
3. How to take Alendronic Acid 70 mg Tablets
4. Possible Side effects
5. How to store Alendronic Acid 70 mg Tablets
6. Further Information

#### 1. WHAT ALENDRONIC ACID 70 MG TABLETS ARE AND WHAT THEY ARE USED FOR

The active ingredient, alendronate monosodium trihydrate belongs to a group of medicines called "bisphosphonates". It works by preventing the loss of the bone that occurs in women after they have been through the menopause, and helps to rebuild bone. Alendronic Acid is used to treat the following condition:

- Postmenopausal osteoporosis

#### 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.

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.

#### How can osteoporosis be treated?

As well as your treatment with Alendronic Acid 70 mg Tablets, 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 (especially calcium and vitamin D)

#### 2. BEFORE YOU TAKE ALENDRONIC ACID 70 MG TABLETS:

If any of the following applies to you, speak to your doctor or pharmacist before you start taking Alendronic Acid 70 mg Tablets as they may not be suitable for you.

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

- If you are allergic (hypersensitive) to alendronate monosodium trihydrate or any of the other ingredients of Alendronic Acid 70 mg Tablets.
- If you have certain disorders of the Oesophagus (the tube that connects your mouth with your stomach).
- If you are unable to stand or sit upright for at least 30 minutes.
- If your doctor has told you that you have very low blood calcium.
- If you are or think you may be pregnant.
- If you are breast-feeding.

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

It is important to tell your doctor before taking Alendronic Acid 70mg Tablets:

- If your doctor has told you that you have Barrett's oesophagus (a condition associated with the changes in the cells that line the oesophagus)
- You suffer from kidney problems
- You have any allergies
- You have trouble swallowing or digestive problems
- You have been told you have low blood calcium levels,
- You have poor dental health, gum disease, a planned dental extraction or you don't receive routine dental care
- You have cancer,
- You are undergoing chemotherapy or radiotherapy,
- 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 have been told you have low blood calcium,
- You are taking angiogenesis inhibitors (such as bevacizumab, or thalidomide) which are used in the treatment of cancer

You may be advised to have a dental check-up before starting treatment with Alendronic Acid 70 mg tablets.

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

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

- After swallowing your tablet, wait at least 30 minutes before taking any other medication for the day. Alendronic Acid 70 mg Tablets are only effective if taken when your stomach is empty.
- It is likely that calcium supplements, antacids and some other medicines will interfere with the absorption of Alendronic Acid 70 mg Tablets if taken at same time. Therefore, it is important that you follow the advice given in section 3.
- Certain medicines for rheumatism or long-term pain called NSAIDs (e.g. acetylsalicylic acid or ibuprofen) might cause digestive problems. Therefore, caution should be used when these medicines are taken at the same time as Alendronic Acid 70 mg Tablets.

#### Taking Alendronic Acid 70 mg Tablets with food and drink:

Patients must wait at least 30 minutes after taking Alendronate before taking any food or drink.

#### Children and adolescents

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

#### Pregnancy and breast-feeding:

Alendronic Acid 70 mg Tablets can not be used during pregnancy and if you are breast-feeding.

#### Driving and using machines:

There have been side effects (for example blurred vision, dizziness and severe bone, muscle or joint pain) reported with Alendronic Acid 70 mg Tablets that may affect your ability to drive or operate machinery (see section 4).

#### Other precautions you should take:

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

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

Your doctor has decided on the dose which is suited to you. The length of your course of treatment will depend on what condition you are suffering from. Always take Alendronic Acid 70 mg tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

You may have previously been prescribed a 10 mg tablet of Alendronate which is taken once a day. One Alendronic Acid 70 mg Tablet is taken once a week.

It is very important that you follow actions 2, 3, 4 and 5 described below. This will help the Alendronic Acid 70 mg

Tablet reach your stomach quickly and help reduce the risk of irritating your oesophagus.

1. Choose the day of the week that best fits your schedule. Every week, take your Alendronic Acid 70 mg Tablet on your chosen day.

2. After getting up for the day and before taking your first food, drink or other medication, swallow your Alendronic Acid 70 mg Tablet with a full glass of plain water only (not less than 200ml or 7fl.oz.).

Do not crush or chew or allow the tablet to dissolve in your mouth because of the possibility of mouth ulceration.

3. After swallowing your Alendronic Acid 70 mg Tablet do not lie down – stay fully upright (or sat upright) for at least 30 minutes and do not lie down until after your first food of the day

4. Do not take Alendronic Acid 70 mg Tablets at bedtime or before getting up for the day.

5. If you develop difficulty or pain swallowing, chest pain, or new or worsening heartburn, stop taking Alendronic Acid 70 mg Tablets and contact your doctor.

6. After swallowing your Alendronic Acid 70 mg Tablet, wait at least 30 minutes before taking your first food, drink or other medication of the day, including antacids, calcium supplements and vitamins. Alendronic Acid 70 mg Tablets are only effective if taken when your stomach is empty.

#### **If you take more Alendronic Acid 70 mg Tablets than you should:**

If you (or someone else) accidentally take too many Alendronic Acid 70 mg Tablets, drink a full glass of milk and contact your doctor or pharmacist immediately.

#### **If you forget to take Alendronic Acid 70 mg Tablets:**

If you forget to take a dose, take one Alendronic Acid 70 mg Tablet on the morning after you remember. Do not take a double dose to make up for forgotten individual doses.

#### **If you stop taking Alendronic Acid 70 mg Tablets:**

Always contact your doctor or pharmacist before you stop taking Alendronic Acid 70 mg Tablets. Alendronic Acid 70 mg Tablet can treat your osteoporosis only if you continue to take the tablets.

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

#### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Alendronic Acid 70 mg 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 skin reactions,
- 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 up to 1 in 10 people):**

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

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

- Stomach pain, constipation, diarrhoea, flatulence, oesophageal ulcer, acid regurgitation, swollen abdomen, swallowing difficulties, digestive problems
- bone, muscle or joint pain
- headache, dizziness
- tiredness, swelling in the hands or legs

- joint swelling
- hair loss, itching

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

- nausea; vomiting,
- Rash, reddening of the skin, itching
- feeling sick, being sick
- swelling of the stomach wall, black or bloody stools, inflammation of the food passage, wearing away of the food passage.
- taste disturbance
- blurred vision; pain or redness in the eye,
- transient flu-like symptoms such as aching muscles, generally feeling unwell and sometimes with fever usually at start of treatment

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

- Allergic reaction including hives and swelling of the lips tongue and throat, fever, discomfort, muscle pain, rash, (occasionally made worse by sunlight), reduced blood calcium levels
- difficulty in swallowing, ulcers of the mouth, stomach and other ulcer (some with bleeding)
- eye pain diminished or hazy vision and/or seeing black floating spots
- Jaw problems such as pain in the jaw (and /or mouth), numbness or a feeling of heaviness in the jaw, or loosening of a tooth, or swelling or sores inside the mouth. These could be signs of the bone damage in the jaw (known as “osteonecrosis”) and may be also associated with delayed healing and infection, often following tooth extraction. Contact your doctor or dentist if anything like this happens to you.
- Usually 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.

##### **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.

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.

##### **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 the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

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

Keep out of the reach and sight of children.

This medical product does not require any special storage conditions.

Do not use Alendronic Acid 70 mg Tablets after the expiry date which is stated on the outer packaging. The expiry date refers to the last day of the month.

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 70 mg Tablets contain**

- The active substance is Alendronate monosodium trihydrate and each tablet contains 70 mg of alendronate monosodium trihydrate.
- The other ingredients are microcrystalline cellulose, crospovidone and magnesium stearate.

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

Each tablet is white, oval, biconvex and marked with a “70” on one side. Alendronic Acid 70 mg Tablets are available in blisters of 4 tablets.

##### **Marketing Authorisation holder:**

Somex Pharma, Seven Kings, Ilford, Essex IG3 8BS UK.

##### **Manufacturer:**

Somex Pharma, Sever Kings, Ilford, Essex, IG3 8RA, UK.

This leaflet was last updated in 02/2024