ALENDRONIC ACID 70 mg TABLETS

1. WHAT ALENDRONIC ACID IS AND WHAT IT IS USED FOR

Alandronic Acid belongs to a group of drugs called bisphosphonates, which prevent bone loss from the body. Alendronic Acid is used to treat osteoporosis (thinning of the bones) in post-menopausal women. Alendronic Acid will reduce your risk of back and hip fractures.

2. BEFORE YOU TAKE ALENDRONIC ACID

Do NOT take Alendronic Acid if you:
• are allergic (hypersensitive) to alendronic acid or any of the other ingredients of this medicine
• suffer from certain disorders of the oesophagus (also called the gullet, 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
• have been told by your doctor that you have low blood calcium or other mineral levels.
If you think any of these apply to you, do not take the tablets. Talk to your doctor first and follow the advice given.

Take special care with Alendronic Acid
It is important to tell your doctor before taking Alendronic acid:
• 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).

Talk to your doctor before you start to take this medicine if you:
• have difficulty swallowing
• have inflammation of the stomach lining or the duodenum (first section of the small intestine)
• have a stomach ulcer or other digestive problems
• have kidney problems
• have cancer (see ‘taking other medicines’ below)
• have poor dental hygiene
• are due to have dental surgery
• have had surgery on your stomach or gullet (not including pyloroplasty where the outlet from the stomach is widened) in the last year
• have had a stomach ulcer or stomach bleeding in the last year

A dental examination should be considered before you start treatment with Alendronic acid if you have any of the conditions below.
• You have cancer

3. HOW TO TAKE ALENDRONIC ACID

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 should follow the instructions below carefully to make sure your medicine is effective and to reduce the risk of your medicine irritating your gullet.

Take special care with Alendronic Acid
It is important to tell your doctor before taking Alendronic acid:
• 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).

Talk to your doctor before you start to take this medicine if you:
• have difficulty swallowing
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• have cancer (see ‘taking other medicines’ below)
• have poor dental hygiene
• are due to have dental surgery
• have had surgery on your stomach or gullet (not including pyloroplasty where the outlet from the stomach is widened) in the last year
• have had a stomach ulcer or stomach bleeding in the last year.

A dental examination should be considered before you start treatment with Alendronic acid if you have any of the conditions below.
• You have cancer
The usual dosage is:

- **Adults (including the elderly)**
  One 70 mg tablet once a week.

- **Children and adolescents**
  Alendronic Acid should not be given to children and adolescents.

If you take more Alendronic Acid than you should

If you (or someone else) swallow a lot of the tablets all together or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. Drink a full glass of milk and do not lie down.

An overdose is likely to cause upset stomach, indigestion, stomach ulcer and painful inflammation of the gullet and stomach. Please take this leaflet, any remaining tablets and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take Alendronic Acid

If you forget to take your tablet when you first get up on your chosen day, take one first thing when you get up the next morning. Never take two doses together or on the same day.

Continue taking one tablet once a week on your chosen day.

If you stop taking Alendronic Acid

Do not stop taking your medicine without talking to your doctor first even if you feel better.

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

### POSSIBLE SIDE EFFECTS

Like all medicines, Alendronic Acid can cause side effects, although not everybody gets them. If the following happens, stop taking the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:

- An allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives).

This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

If the following happens, stop taking your tablets and tell your doctor immediately:

- Difficulty or pain when swallowing, pain behind the breastbone (centre of the chest), new or worsening heartburn.

If the following happens, tell your doctor immediately:

- Blistering of the skin, eyes, mouth and genitals.

Unusual fractures 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.

The following side effects have been reported at the approximate frequencies shown:

<table>
<thead>
<tr>
<th>Side Effect</th>
<th>Frequency</th>
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<tbody>
<tr>
<td>Pain in the bones, muscles or joints</td>
<td>Very Common (may affect more than 1 in 10 people)</td>
</tr>
<tr>
<td>Abdominal pain, indigestion or heartburn, constipation, diarrhoea, wind</td>
<td>Common (may affect up to 1 in 10 people)</td>
</tr>
<tr>
<td>Ulceration of the gullet which can cause chest pain, heart burn or difficulty in swallowing, difficulty swallowing, full or bloated feeling in the stomach, belching after eating, regurgitation of acid from the stomach</td>
<td>Uncommon (may affect up to 1 in 10 people)</td>
</tr>
<tr>
<td>Headache</td>
<td>Uncommon (may affect up to 1 in 10 people)</td>
</tr>
<tr>
<td>Dizziness</td>
<td>Very rare</td>
</tr>
<tr>
<td>Vertigo</td>
<td>Rare</td>
</tr>
<tr>
<td>Hair loss (alopecia), itching (pruritus)</td>
<td>Very rare</td>
</tr>
<tr>
<td>Joint swelling</td>
<td>Very rare</td>
</tr>
<tr>
<td>Weakness and loss of strength (asthenia), swelling of tissues (peripheral oedema)</td>
<td>Very rare</td>
</tr>
<tr>
<td>Rash and reddening of the skin</td>
<td>Very rare</td>
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<tr>
<td>Feeling sick, being sick, inflammation of the stomach, inflammation and/or erosion of the gullet or stomach, black tarry stools</td>
<td>Very rare</td>
</tr>
<tr>
<td>Distortion of the sense of taste (dysgeusia)</td>
<td>Very rare</td>
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<tr>
<td>Eye inflammation (uveitis, scleritis, episcleritis)</td>
<td>Very rare</td>
</tr>
<tr>
<td>Transient flu-like symptoms, such as aching muscles, a general feeling of being unwell and sometimes fever (usually at the start of treatment)</td>
<td>Very rare</td>
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<tr>
<td>Rare (may affect up to 1 in 10,000 people)</td>
<td></td>
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<tr>
<td>Symptoms of low blood calcium levels including muscle cramps or spasms and/or tingling sensation in the fingers or around the mouth</td>
<td>Very rare</td>
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<tr>
<td>Jaw problems associated with delayed healing and infection, often following tooth extraction. This has mainly been reported in patients treated for cancer, but some cases have also been reported in patients treated for osteoporosis.</td>
<td>Very rare</td>
</tr>
<tr>
<td>Rash made worse by sunlight (sensitivity to light)</td>
<td>Very rare</td>
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<tr>
<td>Blurred vision, pain or redness in the eye</td>
<td>Very rare</td>
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<tr>
<td>Mouth ulcers when the tablets have been chewed or sucked</td>
<td>Very rare</td>
</tr>
<tr>
<td>Gullet narrowing, stomach and other peptic ulcers and bleeding (although it is not clear whether these are caused by alendronic acid)</td>
<td>Very rare</td>
</tr>
<tr>
<td>Severe skin reactions.</td>
<td>Very rare</td>
</tr>
</tbody>
</table>

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 or pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### HOW TO STORE ALENDRONIC ACID

Keep out of the reach and sight of children.

Do not use Alendronic Acid after the expiry date that is stated on the outer packaging. The expiry date refers to the last day of that 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.

### FURTHER INFORMATION

**What Alendronic Acid tablets contain:**

- The active ingredient is alendronic acid (as sodium monohydrate).
- The other ingredients are microcrystalline cellulose (E460), croscarmellose sodium and magnesium stearate.

**What Alendronic Acid tablets look like and contents of the pack:**

- The Alendronic Acid tablets are white to off-white, flat-faced, bevel-edged round tablets, debossed with ‘T’ on one side and plain on the other side.
- The product is available in pack sizes of 2, 4, 8, 12, 40, and 50 tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

The Marketing Authorisation holder and company responsible for manufacture: TEVA UK Limited, Eastbourne, BN22 9AG.

This leaflet was last revised: 11/2015

PL 00289/0889
Teva Pharmaceuticals Europe B.V

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APPROVALS

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