

## Package leaflet: information for the user

# Alendronic Acid 70 mg Tablets Once Weekly

**Read all of this leaflet carefully before you start using 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 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 Alendronic Acid 70 mg Tablets is and what it is used for
2. What you need to know 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. Contents of the pack and other information

### **1. What Alendronic Acid 70 mg Tablets is and what it is used for**

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

### **2. What you need to know before you take Alendronic Acid 70 mg Tablets**

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

- If you are allergic to alendronic acid or any of the other ingredients of this medicine (listed in section 6)
- If you suffer from certain disorders of the oesophagus (also called the gullet, the tube that connects your mouth with your stomach)
- If you are unable to stand or sit upright for at least 30 minutes
- If you have been told by your doctor that you have low blood calcium levels.

#### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Alendronic Acid 70 mg Tablets:

- If you have difficulty swallowing
- 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 inflammation of the stomach lining or the duodenum (first section of the small intestine)
- If you have had surgery on your stomach or gullet (not including pyloroplasty where the outlet from the stomach is widened) in the last year
- If you have a stomach ulcer or other digestive problems
- If you have kidney problems.

#### **It is important to tell your doctor before you take Alendronic Acid 70 mg Tablets**

- If you have cancer
- If you are undergoing chemotherapy or radiotherapy
- If you are taking steroids
- If you are not receiving routine dental care
- If you have gum disease
- If you smoke

Appropriate preventive dental care, as recommended by the dentist, should be followed during treatment.

#### **Other medicines** and Alendronic Acid 70 mg Tablets

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

Talk to your doctor before you take non-steroidal anti-inflammatory drugs (NSAID's) while taking Alendronic Acid. Do not take any other oral medication at the same time as taking this medicine. If you are taking any other oral medication you should leave at least 30 minutes between your dose of this medicine and your other medication.

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

These tablets should be taken on an empty stomach as food and drink can greatly reduce the effectiveness of the medicine. Take the tablets at least 30 minutes before your first meal of the day.

#### **Children and Adolescents:**

Alendronic Acid 70 mg Tablets should not be given to children and adolescents.

#### **Pregnancy and breast-feeding**

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**

In some cases this medicine may cause adverse reactions that may affect your ability to drive or operate machinery (like problems with sight). Do not drive or operate machinery if you are affected.

### **3. How to take Alendronic Acid 70 mg Tablets**

#### **Once Weekly**

Always take this medicine as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor has decided the dose which is suited to you.

The following instructions are particularly important to ensure your medicine is effective and to reduce the potential for the medicine to irritate your oesophagus (the tube that connects your mouth with your stomach):

- Choose the day of the week when you will take your tablet that best fits your schedule. Every week, take one Alendronic Acid 70 mg Tablet on your chosen day
- Your medicine should be taken on an empty stomach immediately on rising in the morning. It should be taken with a full glass of plain water (not tea, coffee, mineral water or juice) half an hour before any food, drink or other medication
- The tablets should be swallowed whole, not chewed or sucked
- Do not lie down after taking your tablet. You must stay upright (sitting, standing or walking) until you have taken your first meal of the day which must be at least half an hour after your dose of Alendronic Acid
- Do not take your tablets at bedtime or before getting out of bed
- If you develop pain or difficulty on swallowing, chest pain or new or worsening heartburn, stop taking this medicine and contact your doctor.

The usual dosage instructions are given below:

Adults (including the elderly): One 70 mg tablet once a week.  
Children and adolescents: Alendronate should not be given to children and adolescents.

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

If you (or someone else) swallow a lot of the tablets altogether 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. Overdose can cause painful muscle spasms, tiredness, weakness, exhaustion and fits. It can also cause an upset stomach, indigestion and painful inflammation of the upper digestive system.

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

If you forget to take a tablet, take one on rising the next morning.

Never take two doses together or on the same day. Return to taking one tablet once a week as originally scheduled on your chosen day.

Do not take a double dose to make up for a forgotten tablet.

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

## 4. Possible side effects

Like all medicines, this medicine can have side effects, although not everybody gets them.

### Serious side effects

As can happen with any medicine, a few people may develop an allergic reaction.

If you experience the following, tell your doctor **immediately** or go to the casualty department at your nearest hospital:

Uncommon: may affect up to 1 in 100 people

- Eye inflammation (usually painful)

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

Allergic reaction, including hives and rapid swelling of the skin and mucous membranes (urticaria and angioedema), difficulty breathing, swelling of the lips, face and neck

- A severe skin reaction with extensive blistering and peeling, which leaves the skin looking scalded (toxic epidermal necrolysis)
- A severe reaction with small blisters on reddish or purplish, flat, thickened patches of skin, including around or in the mouth and/or eyes and/or genital area (Stevens-Johnson syndrome).
- Rash on exposure to sunlight
- Jaw problems (generally following tooth extraction and/or local infection)
- Unusual 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 you develop difficulty or pain when swallowing, pain behind the breastbone (centre of the chest), or new or worsening heartburn, **stop taking your tablets and contact your doctor.**

### Other side effects

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

Very common: may affect more than 1 in 10 people

- Pain in the bones, muscles or joints, sometimes severe

Common: may affect up to 1 in 10 people

- Abdominal pain, indigestion or heartburn, constipation, diarrhoea, wind
- Ulcer of the oesophagus (gullet), difficulty swallowing, full or bloated feeling in the stomach, regurgitation of acid from the stomach
- Headache, dizziness
- Joint swelling, swelling in the hands or legs (oedema)
- Itching, hair loss
- Tiredness.

Uncommon: may affect up to 1 in 100 people

- Rashes and reddening of the skin
- Nausea (feeling sick), vomiting (being sick), inflammation of the gullet or stomach, damage to the surface of the gullet which may cause pain and difficulty swallowing, black tarry stools
- Changes in the sense of taste
- Transient symptoms (pain in the muscles, malaise and rarely fever) at the initiation of the treatment.

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

- Low blood calcium levels

- Narrowing of the gullet, mouth, stomach and other peptic ulcers

Blood calcium and phosphate levels may be affected by Alendronic Acid, but you may not experience 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.

Osteonecrosis (arthritis) of the jaw (jaw problems, generally following tooth extraction and/or local infection) has been reported in patients treated with bisphosphonates including alendronic acid. Osteonecrosis of the jaw has mainly been reported in patients treated for cancer, but some cases have also been reported in patients treated for osteoporosis.

### 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto: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 70 mg Tablets

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

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the outer packaging.

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 to protect the environment.

## 6. Contents of the pack and other information

### What Alendronic Acid 70 mg Tablets contains

- The active ingredient is alendronic acid. Each tablet contains 70 mg alendronic acid (as sodium monohydrate).
- The other ingredients are microcrystalline cellulose, croscarmellose sodium and magnesium stearate.

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

The name of your medicine is Alendronic Acid 70 mg Tablets Once Weekly. The product is available in a pack of 4 tablets.

### Product procured from within the EU by the Parallel Product Authorisation Holder:

WPR Healthcare Limited, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath.

### Product repackaged and distributed by:

PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath.

**Parallel Product Authorisation Number:** PPA 565/58/1

### Manufacturer:

TEVA UK Limited, Eastbourne, BN22 9AG, UK

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