

ALENDRONATE SANDOZ TABLET

Alendronic acid (70 mg)

What is in this leaflet:

1. What Alendronate Sandoz is used for
2. How Alendronate Sandoz works
3. Before you use Alendronate Sandoz
4. How to use Alendronate Sandoz
5. While you are using Alendronate Sandoz
6. Side effects
7. Storage and disposal Alendronate Sandoz
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Alendronate Sandoz is used for
Your doctor has prescribed Alendronate Sandoz to treat your osteoporosis.

Osteoporosis is a thinning and weakening of the bones. It is common in women after the menopause. At 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 Alendronate Sandoz works

Alendronate belongs to a group of non-hormonal medicines called bisphosphonates. Alendronate prevents the loss of bones 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.

Before you use Alendronate Sandoz

- When you must not use it

Do not take Alendronate Sandoz:

- If you are hypersensitive (allergic) to alendronate sodium trihydrate, other bisphosphates or any of the other

ingredients of Alendronate Sandoz (see section **Product Description**).

- 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.

Children and adolescents

Alendronate Sandoz should not be given to children and adolescents.

Pregnancy and breast-feeding

Pregnancy

You should not take Alendronate Sandoz if you think you are or think you may be pregnant. Alendronate Sandoz is only intended for use in postmenopausal women.

Breast-feeding

You should not take Alendronate Sandoz if you are breast-feeding. Alendronate Sandoz is only intended for use in postmenopausal women.

- Before you start to use it

Tell your doctor if you have or have had any medical condition especially the following:

- If you suffer from kidney problems
- If you have any swallowing or digestive problems, or a history of severe gastrointestinal problems in past one year, such as gastric ulcer or gastric bleeding
- If you have low blood calcium levels.

You may be advised to have a dental check-up before starting treatment with Alendronate Sandoz. Tell your doctor if you currently have any of the following, which may increase your risk of getting jaw bone problems:

- Problems with your teeth, mouth or gums, such as pain or swelling of your gums and/ or jaw, numbness of the jaw, if the jaw feels heavy or if you have lost a tooth
- Cancer, radiotherapy or chemotherapy treatment
- Infection

- You are taking steroids
- You are planning to have any dental procedures such as tooth extraction or other oral surgery
- You do not regularly look after your teeth or see a dentist

- Taking other medicines

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

- Any hormone or glucocorticoid medicines
- Nonsteroidal anti-inflammatory drugs (NSAID)

It is likely that calcium supplements, antacids, and some oral medicines will interfere with the absorption of Alendronate Sandoz if taken at the same time. Therefore, it is important that you follow the advice given in section "**How to use Alendronate Sandoz**".

Taking Alendronate Sandoz with food and drink

It is likely that food and beverages (including mineral water) will make Alendronate Sandoz less effective if taken at the same time. Therefore, it is important that you follow the advice given in section "**How to use Alendronate Sandoz**".

How to use Alendronate Sandoz

- How much to use

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

Take one 70mg film-coated tablet once a week.

Follow these instructions carefully to make sure you will benefit Alendronate Sandoz:

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

It is very important to follow instructions 2), 3), 4) and 5) to help the Alendronate Sandoz reach your stomach quickly and help reduce the chance of irritating your gullet (oesophagus - the tube

ALENDRONATE SANDOZ TABLET

Alendronic acid (70 mg)

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 Sandoz 70 mg Film-coated tablet with a full glass of water only (not mineral water) (not less than 200ml 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 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 Alendronate Sandoz 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 Alendronate Sandoz and contact your doctor.
- 7) After swallowing your Alendronate Sandoz, wait at least 30 minutes before taking your first food, drink, or other medicine of the day, including antacids, calcium supplements and vitamins. Alendronate Sandoz is effective only if taken when your stomach is empty.
- 8) It is important that you continue taking Alendronate Sandoz for as long as your doctor prescribes the medicine. Alendronate Sandoz can treat your osteoporosis only if you continue to take the tablets.

- When to use it

Always take this medicine exactly as your doctor told you. Please ask your doctor or pharmacist if you are not sure (see also *How much to use*).

- How long to use it

It is important to take your medicine every day. Always consult your doctor, if you wish to stop taking this medicine. Even if you feel well, it may be necessary to continue taking this medicine. If you have any further questions on the use of this product, ask your doctor or pharmacist.

- If you forget to use it

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 use too much (overdose)

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 take too much Alendronate Sandoz, you may have an upset stomach, heartburn, or ulcer.

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

While you are using it

- Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell your doctors, dentists and pharmacists treating you that you are taking Alendronate Sandoz.
- Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

- Do not take any new medicines without consulting your doctor or pharmacist.
- Do not give Alendronate Sandoz to anyone else, even if they have the same symptoms are condition as you.
- Do not stop taking the medicine unless advised by your doctor.

- Things to be careful of

Driving and using machines

Do not drive a car or operate machinery until you know how Alendronate Sandoz affects you.

Risks of oesophageal irritation

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 Alendronate Sandoz. These side effects may worsen if patients continue to take Alendronate Sandoz after developing these

symptoms.

Diet

Make sure you are taking enough calcium and Vitamin D in your diet. Your doctor, pharmacist, or dietitian can tell you what foods you should eat, and whether you should take a supplement.

Good oral hygiene

Make sure you keep up good oral hygiene practices. Clean your teeth regularly and visit your dentist routinely. Tell your dentist that you are taking Alendronate Sandoz, as some dental treatments may not be recommended for you. (See also *Before you start to use it*)

Side effects

Like all medicines, Alendronate Sandoz can cause side effects, although not everybody gets them.

Tell your doctor if you notice any of the following and they worry you:

Very common side effects:

- Musculoskeletal pain (bone, muscle or joint) which is sometimes severe

Common side effects:

- Headache, dizziness
- Vertigo
- Abdominal pain
- Constipation
- Diarrhea
- Excessive stomach or intestinal gas (flatulence)
- Acid regurgitation where acid from the stomach escapes into the gullet (the tube which connects your throat to your stomach)
- Itching of the skin (pruritus)
- Baldness
- Joint swelling
- Swelling of lower limbs

Uncommon side effects:

- Nausea
- Vomiting
- Inflammation of the stomach lining (gastritis)
- Inflammation of the oesophagus (oesophagitis)
- Black and tarry faeces (melaena)
- Inflammation of the eye parts such as uvea (uveitis), sclera (scleritis),

ALENDRONATE SANDOZ TABLET

Alendronic acid (70 mg)

episclera (episcleritis)

- Rash
- Redness of the skin (erythema)
- Feeling tired and rarely fever

Rare side effects:

- Allergic reaction such as hives (urticaria), swelling of the face, lips, hands or feet (angioedema)
- Low blood calcium levels
- Perforation of oesophagus
- Skin disorders including Stevens-Johnson syndrome and toxic epidermal necrolysis. Tell your doctor immediately if your skin starts to turn red and then blister or peel.
- Osteonecrosis of the jaw bone. Tell your doctor immediately if you notice any jaw bone problems (see also *Before you start to use it*)

Very rare side effects:

- 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. Other side effects not listed above may occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of Alendronate Sandoz

- Storage

Keep out of the reach and sight of children.

Do not take the tablets after the expiry date stated on the blister and the carton. Store below 30°C in the original package.

- Disposal

Medicinal 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.

Product Description

- What it looks like

White, round, biconvex film coated tablet, debossed with “ALN 70” on one side.

- Ingredients

Active ingredients

The active substance is sodium alendronate. Each film-coated tablet contains 70mg alendronic acid (as sodium alendronate trihydrate).

Inactive ingredients

Tablet core:

Microcrystalline cellulose
Colloidal anhydrous silica,
Croscarmellose sodium
Magnesium stearate

Tablet coating:

Microcrystalline cellulose
Carrageenan
Macrogol

- MAL Number

MAL10080040ACZ

Manufacturer

Novartis Pharmaceutical Manufacturing LLC
Verovškova ulica 57, 1000 Ljubljana, Slovenia.

Product registration holder

Sandoz Products Malaysia Sdn. Bhd.
3A-2 & 3A-3, Level 3A, Menara KEN TTDI,
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