

Package leaflet: Information for the patient

Alendroninezuur/Cholecalciferol Sandoz® 70 mg/5600 IE, tabletten alendronic acid/colecalciferol

Read all of this leaflet carefully before you start taking 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.

It is particularly important to understand the information in section “3. How to take [Nationally completed name]”, before taking this medicine.

What is in this leaflet

1. What [Nationally completed name] is and what it is used for
2. What you need to know before you take [Nationally completed name]
3. How to take [Nationally completed name]
4. Possible side effects
5. How to store [Nationally completed name]
6. Contents of the pack and other information

1. What [Nationally completed name] is and what it is used for

What is [Nationally completed name]?

[Nationally completed name] is a tablet containing the two active substances, alendronic acid (commonly called alendronate) and colecalciferol known as vitamin D₃.

What is alendronate?

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

What is vitamin D?

Vitamin D is an essential nutrient, required for calcium absorption and healthy bones. The body can only absorb calcium properly from our food if it has enough vitamin D. Very few foods contain vitamin D. The main source is through exposure to summer sunlight, which makes vitamin D in our skin. As we get older our skin makes less vitamin D. Too little vitamin D may lead to bone loss and osteoporosis. Severe vitamin D deficiency may cause muscle weakness which can lead to falls and a greater risk of fractures.

What is [Nationally completed name] used for?

Your doctor has prescribed [Nationally completed name] to **treat** your **osteoporosis** and because you are at risk of vitamin D insufficiency. [Nationally completed name] reduces the risk of spine and hip fractures in women after menopause.

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 [Nationally completed name], 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.

2. What you need to know before you take [Nationally completed name]

Do not take [Nationally completed name]

- if you are **allergic** to alendronate sodium trihydrate, colecalciferol or any of the other ingredients of this medicine (listed in section 6)
- 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.

Warnings and precautions

Talk to your doctor or pharmacist before taking [Nationally completed name] if:

- you suffer from kidney problems

- you have, or have recently had, any swallowing or digestive problems
- your doctor has told you that you have Barrett's oesophagus (a condition associated with changes in the cells that line the lower oesophagus)
- you have been told you have trouble absorbing minerals in your stomach or intestines (malabsorption syndrome),
- 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 angiogenesis inhibitors (such as bevacizumab, or thalidomide) which are used in the treatment of cancer
- 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 may be advised to have a dental check-up before starting treatment with [Nationally completed name].

It is important to maintain good oral hygiene when being treated with [Nationally completed name]. 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.

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 [Nationally completed name]. These side effects may worsen if patients continue to take [Nationally completed name] after developing these symptoms.

Children and adolescents

[Nationally completed name] should not be given to children and adolescents less than 18 years of age.

Other medicines and [Nationally completed name]

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

It is likely that calcium supplements, antacids, and some oral medicines will interfere with the absorption of [Nationally completed name] if taken at the same time. Therefore, it is important that you follow the advice given in section “3. How to take [Nationally completed name]” and **wait at least 30 minutes before taking** any other **oral medicines or supplements**.

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 [Nationally completed name].

It is likely that certain medicines or food additives may prevent the vitamin D in [Nationally completed name] from getting into your body, including artificial fat substitutes, mineral oils, the

weight loss medicine, orlistat, and the cholesterol-lowering medicines, cholestyramine and colestipol. Medicines for fits (seizures) (like phenytoin or phenobarbital) may decrease the effectiveness of vitamin D. Additional vitamin D supplements may be considered on an individual basis.

[Nationally completed name] with food and drink

It is likely that food and beverages (including mineral water) will make [Nationally completed name] less effective if taken at the same time. Therefore, it is important that you follow the advice given in section “3. How to take [Nationally completed name]”. You must **wait at least 30 minutes before taking any food and beverages** except water.

Pregnancy and breast-feeding

[Nationally completed name] is only intended for use in postmenopausal women. You should **not take** [Nationally completed name] if you are or think you may be pregnant, or 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 alendronate/ colecalciferol that may affect your ability to drive or operate machinery. (See section 4. “Possible side effects”.) If you experience any of these side effects you should not drive until you feel better.

[Nationally completed name] contains sucrose and sodium

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

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take [Nationally completed name]

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

Take one [Nationally completed name] tablet once a week.

Follow these instructions carefully.

- 1) Choose the day of the week that best fits your schedule. Every week, take one [Nationally completed name] tablet on your chosen day.

It is very important to follow instructions 2), 3), 4) and 5) to help the [Nationally completed name] tablet reach your stomach quickly and help reduce the chance of irritating your gullet (oesophagus - the tube 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 [Nationally completed name] **tablet whole with a full glass of water** only (not mineral water) (not less than 200 ml), so that [Nationally completed name] is adequately absorbed.
 - Do not take with mineral water (still or sparkling).
 - Do not take with coffee or tea.
 - Do not take with juice or milk.

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

- 3) **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.
- 4) Do not take [Nationally completed name] at bedtime or before getting up for the day.
- 5) If you develop difficulty or pain upon swallowing, chest pain, or new or worsening heartburn, stop taking [Nationally completed name] and contact your doctor.
- 6) After swallowing your [Nationally completed name] tablet, **wait at least 30 minutes before taking your first food, drink, or other medicine** of the day, including antacids, calcium supplements and vitamins. [Nationally completed name] is effective only if taken when your stomach is empty.

If you take more [Nationally completed name] than you should

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 forget to take [Nationally completed name]

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 stop taking [Nationally completed name]

It is important that you take [Nationally completed name] for as long as your doctor prescribes the medicine. Since it is not known how long you should take [Nationally completed name], you should discuss the need to stay on this medicine with your doctor periodically to determine if [Nationally completed name] is still right for you.

A paragraph containing instructions is added at the end of this package leaflet. It contains important information reminding you how to take [Nationally completed name] properly.

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 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.

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.

Other side effects include:

Very common (may affect more than 1 in 10 people)

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

Common (may affect up to 1 in 10 people)

- joint swelling
- abdominal pain, uncomfortable feeling in the stomach or belching after eating, constipation, full or bloated feeling in the stomach, diarrhoea, flatulence
- hair loss, itching
- headache, dizziness
- tiredness, swelling in the hands or legs

Uncommon (may affect up to 1 in 100 people)

- nausea, vomiting
- irritation or inflammation of the gullet (oesophagus - the tube that connects your mouth with your stomach) or stomach
- black or tar-like stools
- blurred vision; pain or redness in the eye
- rash; redness of the skin
- transient flu-like symptoms, such as aching muscles, generally feeling unwell and sometimes with fever usually at the start of treatment
- taste disturbance

Rare (may affect up to 1 in 1,000 people)

- symptoms of low blood calcium levels including muscle cramps or spasms and/or tingling sensation in the fingers or around the mouth
- stomach or peptic ulcers (sometimes severe or with bleeding)

- narrowing of the gullet (oesophagus - the tube that connects your mouth with your stomach)
- rash made worse by sunlight
- mouth ulcers

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 national reporting system listed in Appendix V**. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store **[Nationally completed name]**

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

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

Store below 25°C. Store in the original package in order to protect from light and moisture.

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 protect the environment.

6. Contents of the pack and other information

What **[Nationally completed name]** contains

- The active substances are alendronic acid and colecalciferol (vitamin D3). Each tablet contains 70 mg alendronic acid as alendronate sodium trihydrate and 140 micrograms (5600 IU) colecalciferol (vitamin D3).
- The other ingredients are microcrystalline cellulose PH112, crospovidone Type A, magnesium stearate, medium-chain triglycerides, modified starch (maize), sucrose, all-rac- α -tocopherol, sodium ascorbate, silica (colloidal anhydrous).

What **[Nationally completed name]** looks like and contents of the pack

White to almost white, oval tablets, debossed with 714 on one side.
Approximately 12.6mm x 6.6mm x 5.2mm.

The tablets are packed in in aluminium/aluminium blisters and inserted in a carton.

Pack sizes:

Blister: 2, 4, 6, 12 tablets

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Houder van de vergunning voor het in de handel brengen

Sandoz B.V., Veluwezoom 22, 1327 AH Almere, Nederland
Correspondentie: Postbus 10332, 1301 AH Almere

Fabrikant

Lek Pharmaceuticals d.d.
Verovškova 57
1526 Ljubljana
Slovenië

In het register ingeschreven onder:

Alendroninezuur/Cholecalciferol Sandoz 70 mg/5600 IE RVG 117969.

Dit medicijn is geregistreerd in lidstaten van de EEA onder de volgende namen:

The Netherlands: Alendroninezuur/Cholecalciferol Sandoz 70 mg/5600IE, tabletten

Germany: Alendron-1 A Pharma plus D 70 mg/5600 i.E. Tabletten

Deze bijsluiter is voor het laatst goedgekeurd in: augustus 2021

IMPORTANT INFORMATION. Please read it carefully.

How to take [Nationally completed name] tablets

1. Take one tablet once a week.
 2. Choose the day of the week that best fits your schedule. When you get out of bed on the day you have chosen, and before taking your first food, drink or other medicines, swallow (do not crush or chew the tablet or allow it to dissolve in your mouth) one [Nationally completed name] tablet with a full glass of water (not mineral water).
 3. Continue your morning activities. You can sit, stand or walk – just stay fully upright. Don't lie down, eat, drink or take other medicines for at least 30 minutes. Do not lie down until after your first food of the day.
 4. Remember, take [Nationally completed name] once each week on that same day for as long as your doctor prescribes it.
- If you miss a dose, take only one [Nationally completed name] 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.