

Package leaflet: Information for the user

Alendronat Sandoz Veckotablett 70 mg Film coated tablets alendronic acid

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 Alendronat Sandoz Veckotablett before taking this medicine.

What is in this leaflet

1. What Alendronat Sandoz Veckotablett is and what it is used for
2. What you need to know before you take Alendronat Sandoz Veckotablett
3. How to take Alendronat Sandoz Veckotablett
4. Possible side effects
5. How to store Alendronat Sandoz Veckotablett
6. Contents of the pack and other information

1. What Alendronat Sandoz Veckotablett is and what it is used for

What is Alendronat Sandoz Veckotablett?

Alendronat Sandoz Veckotablett is a film-coated tablet containing the active substance alendronate sodium.

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 Alendronat Sandoz Veckotablett used for?

Your doctor has prescribed Alendronat Sandoz Veckotablett to treat your osteoporosis. Alendronat Sandoz Veckotablett reduces the risk of spine and hip fractures.

Alendronat Sandoz Veckotablett is a once weekly treatment.

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?

Osteoporosis can be treated and it is never too late to begin treatment. Alendronat Sandoz Veckotablett not only prevents the loss of bone but actually helps to rebuild bone you may have lost and reduces the risk of bones breaking in the spine and hip.

As well as your treatment with Alendronat Sandoz Veckotablett, 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. What you need to know before you take Alendronat Sandoz Veckotablett

Do not take Alendronat Sandoz Veckotablett

- if you are allergic to alendronic acid 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 before taking Alendronat Sandoz Veckotablett

- if you suffer from kidney problems
- if you have any swallowing or digestive problems
- if you have low blood calcium levels
- 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 are aware that the absorption of minerals from the digestive tract is impaired (malabsorption syndrome)
- if you have gum disease, planned dental extraction, poor dental health or you don't receive routine dental care
- if you have cancer
- if you are undergoing chemotherapy or radiotherapy
- if you are taking angiogenesis inhibitors (such as bevacizumab, or thalidomide), which are used in the treatment of cancer

- if you are taking corticosteroids (such as prednisone or dexamethasone), which are used to treat conditions such as asthma, rheumatoid arthritis and severe allergies
- if 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 Alendronat Sandoz Veckotablett. It is important to maintain good oral hygiene when being treated with Alendronat Sandoz Veckotablett. 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 within less than 30 minutes after taking Alendronat Sandoz Veckotablett. These side effects may worsen if patients continue to take Alendronat Sandoz Veckotablett after developing these symptoms.

Children and adolescents

Alendronat Sandoz Veckotablett should not be given to children and adolescents under the age of 18.

Other medicines and Alendronat Sandoz Veckotablett

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 Alendronat Sandoz Veckotablett if taken at the same time. Therefore, it is important that you follow the advice given in section 3. "How to take Alendronat Sandoz Veckotablett".

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 Alendronat Sandoz Veckotablett.

Alendronat Sandoz Veckotablett with food and drink

It is likely that food and beverages (including mineral water) will make Alendronat Sandoz Veckotablett less effective if taken at the same time. Therefore, it is important that you follow the advice given in section 3. "How to take Alendronat Sandoz Veckotablett".

Pregnancy and breast-feeding

Alendronat Sandoz Veckotablett is only intended for use in postmenopausal women.

You should not take Alendronat Sandoz Veckotablett if you are or think you may be pregnant.

You should not take Alendronat Sandoz Veckotablett if you are breast-feeding.

Driving and using machines

Alendronat Sandoz Veckotablett can impair your ability to react or drive. Patients taking Alendronat Sandoz Veckotablett can suffer from side effects including blurred vision, dizziness, severe muscle, joint and bone pain, which may affect your ability to drive or use machines. If you are affected in this way, you should contact your doctor before driving or using machinery. Individual responses to Alendronat Sandoz Veckotablett may vary (See section 4).

Alendronat Sandoz Veckotablett contains sodium

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

3. How to take Alendronat Sandoz Veckotablett

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

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

Follow these instructions carefully to make sure you will benefit from Alendronat Sandoz Veckotablett.

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

It is very important to follow instructions 2), 3), 4) and 5) to help the Alendronat Sandoz Veckotablett 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 alendronate 70 mg Film-coated tablet whole with a full glass of tap water only (not mineral water) (not less than 200 ml or 7 fl. oz.), so that alendronate is sufficiently absorbed by the body.

- 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 or crush the tablet or allow it to dissolve in your mouth, in order to avoid mouth ulcers.

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 meal of the day.

5) Do not take Alendronat Sandoz Veckotablett 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 Alendronat Sandoz Veckotablett and contact your doctor.

7) After swallowing your Alendronat Sandoz Veckotablett, wait at least 30 minutes before taking your first meal, drink, or other medicine of the day, including antacids, calcium supplements and vitamins. Alendronat Sandoz Veckotablett is effective only if taken when your stomach is empty.

If you take more Alendronat Sandoz Veckotablett than you should

If you take more than one tablet at a time 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 Alendronat Sandoz Veckotablett

If you miss a dose, just take one tablet the next morning after you realise you have missed it. 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 Alendronat Sandoz Veckotablett

It is important that you continue taking Alendronat Sandoz Veckotablett for as long as your doctor prescribes the medicine. Since it is not known how long you should take Alendronat Sandoz Veckotablett, you should discuss the need to stay on this medicine with your doctor periodically to determine if Alendronat Sandoz Veckotablett is still right for you.

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 such as ring-shaped, red and often blistering rashes - common on hands and feet (toxic epidermal necrolysis), mucosal and skin inflammation in combination with high fever (Stevens-Johnson syndrome)
- 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 wound healing and infection, often following tooth extraction. Contact your doctor and dentist if you experience such symptoms
- unusual (atypical) fracture of the thigh bone (femur), particularly in patients on long-term treatment for osteoporosis. 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
- severe bone, muscle and/or joint pain

Not known (cannot be estimated from the available data)

- unusual fractures in bones other than the femur

Other side effects that may occur:

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)

- headache
- dizziness
- vertigo
- abdominal pain
- uncomfortable feeling in the stomach or belching after eating
- constipation
- bloating or distended abdomen
- diarrhoea
- flatulence
- joint swelling
- hair loss
- itching
- 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
- skin 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
- blurred vision; pain or redness in the eye

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

- narrowing of the gullet (oesophagus - the tube that connects your mouth with your stomach)
- mouth ulcers
- stomach or intestinal ulcers (sometimes severe or with bleeding)
- skin rash made worse by sunlight
- symptoms of low blood calcium levels including muscle cramps or spasms and/or tingling sensation in the fingers or around the mouth.

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.

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 Alendronat Sandoz Veckotablett

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 and the blister after “EXP”. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 Alendronat Sandoz Veckotablett contains

The active substance is alendronic acid.

Each film-coated tablet contains 70 mg alendronic acid (as sodium trihydrate).

The other ingredients are microcrystalline cellulose, colloidal anhydrous silica, croscarmellose sodium, magnesium stearate, carrageenan, macrogol.

What Alendronat Sandoz Veckotablett looks like and contents of the pack

White, round, biconvex film-coated tablet, debossed with “ALN 70” on one side, with a diameter of approximately 10 mm.

The film-coated tablets are packed in OPA-Aluminium-PVC/Aluminium blister which are inserted in a carton.

Pack sizes:

Blister: 2, 4, 6, 8, 12, 14 film-coated tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[to be completed nationally]

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

[To be completed nationally]

This leaflet was last revised in 2026-02-20.

[To be completed nationally]