

Package leaflet: Information for the user Alendronic Acid Accord 70 mg Tablets Alendronic Acid

Read the entire 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.
- Do you have any questions? Then contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed only for you. It may harm others, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.
- It is especially important that you understand the information given in section 3, "How to use this medicine?" before you start using this medicine.

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1. What is Alendronic Acid Accord and what is it used for?

Alendronic Acid Accord is a tablet containing the active substance alendronic acid (often called alendronate) and belongs to a group of non-hormonal medicines called bisphosphonates. Alendronic acid prevents bone loss that occurs in women after menopause and helps to rebuild bone. It reduces the risk of spinal and hip fractures.

What is this medicine used for?

Your doctor has prescribed Alendronic Acid Accord to treat your osteoporosis. Alendronic Acid Accord reduces the risk of fractures in the spine and hip.

Alendronic Acid Accord is a once-weekly treatment

What is osteoporosis?

Osteoporosis is the thinning and weakening of the bones. It often occurs in women after menopause. During menopause, the ovaries stop producing the female hormone estrogen, which helps keep a woman's skeleton healthy. This leads to bone loss and the bones become weaker. The earlier a woman enters menopause, the greater the risk of osteoporosis.

Initially, osteoporosis usually does not cause symptoms. But if it is not treated, it can lead to broken bones. Although these usually hurt, fractures in the bones of the spine can go unnoticed until they cause loss of height. Bone fractures can occur during normal, everyday activities, such as lifting, or from minor injuries that would not normally break a healthy bone. Fractures usually

occur in the hip, spine, or wrist and can not only lead to pain but also to significant problems such as a stooped posture (hump) and reduced mobility.

How can osteoporosis be treated?

In addition to treatment with Alendroninezuur Accord, your doctor may suggest lifestyle changes to improve your condition, such as:

Stop smoking: Smoking appears to increase the rate of bone loss and may therefore increase the risk of fractures. Smoking seems to accelerate the rate of bone loss and can therefore increase the risk of fractures.

Physical exercise: Eat a balanced diet:

Eat balanced: 2. When should you not use this medicine or be extra careful?

When should you not use this medicine?

You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.

- You have certain problems with your esophagus (the tube that connects your mouth to your stomach), such as narrowing or difficulty swallowing.
- You cannot stand or sit upright for at least 30 minutes.
- Your doctor has told you that you have low blood calcium levels.
- If you think any of these apply to you, do not take the tablets. Consult your doctor first and follow the given advice.
- When should you be extra careful with this medicine?

When should you be extra careful with this medication?

Contact your doctor or pharmacist before using this medicine.

It is important that you inform your doctor before taking Alendroninezuur Accord if

- you have kidney problems
- you have swallowing or digestive problems or have recently been told by your doctor that you have Barrett's esophagus (a condition of the lower esophagus where the lining has changed)
- you have been told that you have problems absorbing minerals in your stomach or intestines (malabsorption syndrome)
- you have been told that you have low calcium levels in your blood
- you have poor dental health or gum disease, or if you need to have a tooth extracted or if you do not regularly visit the dentist for check-ups
- you have cancer
- you are undergoing chemotherapy or radiation therapy
- you are taking medicines called angiogenesis inhibitors (such as bevacizumab or thalidomide) used in cancer treatment
- you are taking medicines called corticosteroids (such as prednisone or dexamethasone) used in the treatment of conditions like asthma, rheumatoid arthritis, and severe allergies,
- you smoke or have smoked in the past (as this can increase the risk of dental problems)

Your doctor may tell you to have a dental check-up before starting treatment with this medicine.

It is important to maintain good oral hygiene when being treated with Alendroninezuur Accord. You should have routine dental check-ups during treatment and contact your doctor or dentist if you experience problems with your mouth or teeth, such as loose teeth, pain, or swelling.

Irritation, inflammation, or ulceration of the esophagus (the tube connecting your mouth to your stomach), often with symptoms of chest pain, heartburn, or difficulty or pain when swallowing, may occur, especially if you do not drink a full glass of water and/or if you lie down less than 30 minutes after taking Alendroninezuur Accord. These side effects may worsen if you continue taking Alendroninezuur Accord after these symptoms develop.

Children and adolescents up to 18 years

Alendroninezuur Accord should not be given to children and adolescents under 18 years.

Are you taking any other medicines?

Are you taking any other medicines besides Alendroninezuur Accord, have you recently done so, or is there a possibility that you will take other medicines in the near future? If so, tell your doctor or pharmacist.

It is likely that calcium supplements, antacids, and some other oral medicines may interfere with the absorption of Alendroninezuur Accord if taken at the same time. It is therefore important that you follow the advice given in the section 'How to use this medicine?'

Certain medicines for rheumatism or long-term pain, called NSAIDs (e.g., acetylsalicylic acid (aspirin) or ibuprofen) can cause digestive problems. Therefore, caution is advised when these medicines are used simultaneously with Alendronic Acid Accord.

What should you pay attention to with food and drink?

It is likely that Alendronic Acid Accord works less well if taken simultaneously with food and drink (including mineral water). Therefore, it is important that you follow the advice given in the section 'How to use this medicine?'

Pregnancy, breastfeeding, and fertility

Alendronic Acid Accord is intended for use only by postmenopausal women. Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

Driving and using machines

Side effects have been reported (including blurred vision, dizziness, and severe bone, muscle, or joint pain) during the use of Alendronic Acid Accord, which may affect your ability to drive and use machines. The reactions to Alendronic Acid Accord can vary from patient to patient (see section 4).

Alendronic Acid Accord contains lactose

If your doctor has told you that you are intolerant to certain sugars, contact your doctor before taking this medicine.

Alendronic Acid Accord contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, which means it is essentially 'sodium-free'.

3. How to use this medicine?

Always take this medicine exactly as your doctor has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

Take one Alendronic Acid tablet once a week.

Follow these instructions carefully to ensure you benefit from alendronic acid.

1) Choose the day of the week that suits you best. Take one Alendronic Acid tablet on the chosen day each week.

It is very important to follow instructions 2), 3), 4), and 5) so that the Alendronic Acid tablet reaches your stomach quickly and there is less chance of irritation of your esophagus (the tube that connects your mouth to your stomach).

2) Take your Alendronic Acid tablet only in the morning after getting up and before eating, drinking, or taking your other medications, with a full glass of water (not mineral water and not less than 200 ml) so that alendronic acid tablets are sufficiently absorbed.

- Do not take with mineral water (with or without carbonation).
- Do not take with coffee or tea.
- Do not take with juice or milk.

Do not crush, chew, or let the tablet dissolve in your mouth due to the possibility of mouth ulcers.

3) Do not lie down – but remain upright (sitting, standing, or walking) for at least 30 minutes after swallowing the tablet. Do not lie down before the first meal of the day.

4) Do not take alendronic acid at bedtime or before getting up.

5) If you experience pain or difficulty swallowing, chest pain, or new or worsening heartburn, stop using alendronic acid and contact your doctor.

6) Wait at least 30 minutes after swallowing your Alendronic Acid tablet before taking the first food, drink, or other medication of the day, including antacids, calcium supplements, and vitamins. Alendronic acid only works if taken on an empty stomach.

Have you taken too much of this medicine?

If you accidentally take too many tablets, drink a full glass of milk and contact your doctor immediately. Do not try to vomit and do not lie down.

Have you forgotten to take this medicine?

If you miss a dose, just take one Alendronic Acid 70 mg tablet the morning after you remember. Do not take a double dose to make up for a forgotten dose. Then continue to take one tablet once a week on your chosen day, as originally planned.

If you stop taking this medicine

It is important that you continue to use Alendronic Acid Accord for as long as your doctor prescribes it. It is not known how long you should take Alendronic Acid Accord. Therefore, consult your doctor from time to time to determine if you should continue taking this medicine and if Alendronic Acid Accord is still the right medicine for you.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

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

Contact your doctor immediately if you experience any of the following side effects. These can be serious and you may need urgent medical attention:

Common (may affect up to 1 in 10 people):

- heartburn, difficulty swallowing, pain when swallowing, ulcers in the esophagus (the tube that connects your mouth to your stomach) that can cause chest pain, heartburn, or difficulty or painful 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, which may cause difficulty breathing or swallowing; severe skin reactions
- pain in the mouth and/or jaw, swelling or sores in the mouth, numbness or a feeling of 'heaviness' in the jaw or loosening of a tooth. These can be signs of bone damage in the jaw (osteonecrosis), which is generally associated with delayed healing and infection, often after a tooth extraction. Contact your doctor and dentist if you experience such symptoms.
- an unusual fracture of the thigh bone can occur, especially in patients treated long-term for osteoporosis. Contact your doctor if you experience pain, weakness, or discomfort in your thigh, hip, or groin. This may be an early indication of a possible fracture of the thigh bone.
- severe bone, muscle, and/or joint pain.
- Other side effects include:
- Very common (may affect more than 1 in 10 people):
- bone, muscle, and/or joint pain that is sometimes severe.

Common (may affect up to 1 in 10 people):

- swelling of the joints
- abdominal pain, discomfort in the stomach or belching after eating, constipation, feeling full or bloated in the abdomen, diarrhea, flatulence
- hair loss, itching
- headache, dizziness
- tiredness, swelling of the hands or legs

Sometimes (may occur in up to 1 in 100 people):

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

Rare (may occur in up to 1 in 1,000 people):

- symptoms of low blood calcium levels including muscle cramps or spasms and/or tingling in the fingers or around the mouth
- stomach and intestinal ulcers (sometimes severe or with bleeding)
- narrowing of the esophagus (the tube that connects your mouth to your stomach)
- rash that worsens with sunlight
- mouth ulcers if the tablets are chewed or sucked

Very rare (may occur in up to 1 in 10,000 people):

- talk to your doctor if you experience ear pain, discharge from the ear and/or ear infection. These could be signs of bone damage in the ear

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb. Website: www.lareb.nl. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How should you store this medicine?

- Keep out of the sight and reach of children.
- There are no special storage conditions for this medicine.
- Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. This refers to the last day of that month.
- 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 does this medicine contain?

The active substance in this medicine is alendronic acid (as sodium alendronate). Each tablet contains 70 mg alendronic acid (as sodium alendronate).

The other ingredients in this medicine are anhydrous lactose, microcrystalline cellulose (E460), croscarmellose sodium, and magnesium stearate.

What does Alendronic Acid Accord look like and what is in the pack?

Alendronic Acid 70 mg tablets are available as white to off-white, oval, biconvex tablets with 'AHL' on one side and no marking on the other side.

Alendronic Acid 70 mg tablets are available in OPA-Al-PVC/Al blisters of 4 or 12 tablets. Not all pack sizes may be marketed.

Marketing authorization holder and manufacturer Marketing authorization holder
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3526 KV Utrecht, Netherlands
Manufacturer

Accord Healthcare Polska Sp.z o.o.,
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This medicine is registered in member states of the EEA under the following names:

Country	Proposed name
Estonia	: Alendronic Acid Accord 70 mg, tablets
Italy	: Alendronato AHCL 70 mg Tablets
Lithuania	: Alendronic Acid Accord 70 mg tablets
Slovenia	: Sodium Alendronate Accord 70 mg Tablets
Netherlands	: Alendronic Acid Accord 70 mg tablets
Cyprus	: Alendronic Acid Once Weekly 70 mg Tablets
Ireland	: Alendronic Acid Once Weekly 70 mg Tablets
United Kingdom	: Alendronic Acid Once Weekly 70 mg Tablets

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