

Package leaflet: Information for the user Alendronic Acid Accord 10 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 that contains the active substance alendronic acid (often called alendronate) and belongs to a group of medicines called bisphosphonates. Alendronic acid prevents bone loss that occurs in women after menopause. It can also prevent bone loss in men or people using steroids, such as prednisolone and methylprednisolone. It has also been shown that alendronic acid helps to rebuild bone in postmenopausal women and men with osteoporosis and reduces the risk of spine and hip fractures.

What is this medicine used for?

Your doctor has prescribed alendronic acid because you have osteoporosis or are at risk of developing this condition.

What is osteoporosis?

Osteoporosis is the thinning and weakening of the bones. It is common in women after menopause. During menopause, the ovaries stop producing the female hormone estrogen, which helps keep the skeleton healthy in women. As a result, bone loss occurs and the bones become weaker. The earlier a woman enters menopause, the greater the risk of osteoporosis. Osteoporosis can also occur in men for several reasons, including aging and/or a low level of the male hormone testosterone. In all cases, bone tissue is broken down faster than it is built up, resulting in bone loss and weaker bones.

Bone loss and osteoporosis can also be caused by corticosteroids in both men and women.

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

How can osteoporosis be treated/prevented?

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

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

Exercise: Like muscles, bones need movement to stay healthy and strong. Consult your doctor before starting an exercise program.

Eat balanced: Your doctor can advise you on your eating habits and whether you should take dietary supplements (especially calcium and vitamin D).

2. When should you not use this medicine or be extra careful with it?

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 cases apply to you, do not take the tablets. First consult your doctor and follow the given advice.

When should you be extra careful with this medicine?

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 part of the esophagus where the lining (esophageal 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 a gum condition, or if you need to have a tooth or molar extracted or if you do not regularly visit the dentist for check-ups
- if you have cancer
- you are receiving chemotherapy or radiation
- you are using medicines called angiogenesis inhibitors (such as bevacizumab or thalidomide) used in the treatment of cancer
- you are using medicines called corticosteroids (such as prednisone or dexamethasone) used in the treatment of conditions such as asthma, rheumatoid arthritis, and severe allergies,
- you smoke or have smoked in the past (as this can increase the risk of dental conditions)

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 develop problems with your mouth or teeth, such as loose teeth, pain, or swelling.

Irritation, inflammation, or ulceration of the esophagus (oesophagus – the tube that connects 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 to take Alendroninezuur Accord after these symptoms have developed.

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

Calcium supplements, antacids, and some oral medications may affect the absorption of Alendroninezuur Accord in the body if taken at the same time as Alendroninezuur Accord. Therefore, it is important to follow the advice given in section 3, "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 Alendroninezuur Accord.

What should you pay attention to with food and drink?

It is likely that this medicine works less well if taken simultaneously with food and drink (including mineral water). Therefore, it is important to follow the advice given in section 3: "How to use this medicine?".

Pregnancy, breastfeeding, and fertility

Alendroninezuur Accord is intended for use only by postmenopausal women. If you are pregnant, breastfeeding, think you may be pregnant, or are planning to have a baby, do not use Alendroninezuur Accord.

Ask your doctor or pharmacist for advice before taking 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 Alendroninezuur Accord, which may affect your ability to drive and use machines. Reactions to Alendroninezuur Accord can vary from patient to patient (see section 4).

Alendroninezuur Accord contains lactose

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

Alendroninezuur Accord contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, meaning 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.

Taking your medicine

It is very important to follow instructions 1 to 5 so that the tablet reaches your stomach quickly and there is less chance of possible irritation of your esophagus (the tube that connects your mouth to your stomach).

1. Take Alendroninezuur Accord in the morning after getting up, and before eating, drinking, or taking other medicines, with a full glass of tap water (not less than 200 ml) so that alendroninezuur tablets are sufficiently absorbed.
 - no mineral water (with or without carbonation)
 - no coffee or tea
 - no juice or milk.
 - Do not crush or chew the tablets and do not let them dissolve in your mouth due to the possibility of mouth ulcers.
2. Do not lie down – but remain upright (sitting, standing, or walking) for at least 30 minutes after swallowing Alendroninezuur Accord. Do not lie down before your first meal of the day.
3. Do not take Alendroninezuur Accord at bedtime or before getting up.
4. If you experience pain or difficulty swallowing, chest pain, or new or worsening heartburn, stop using Alendroninezuur Accord and contact your doctor immediately.

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

The recommended dosage

- for the treatment of osteoporosis in men or postmenopausal women is the recommended dose of one 10 mg tablet once daily.
- for the treatment and prevention of glucocorticoid-induced osteoporosis in postmenopausal women not receiving hormone replacement therapy (HRT) with estrogen, the usual dose is 10 mg once daily.

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, skip it.
- Take the next dose at the usual time.
- Do not take a double dose to make up for a forgotten dose.

If you stop taking this medicine

It is important that you continue taking Alendroninezuur Accord as long as your doctor prescribes it. It is not known how long you may take Alendroninezuur Accord. Therefore, consult your doctor from time to time to determine whether you should continue taking this medicine and whether Alendroninezuur 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) which can cause chest pain, heartburn, or difficulty or pain when 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 reactions on your skin, mucous

membranes in your mouth or nose, your eyes or your genitals. If you experience these symptoms, stop using this medicine and contact your doctor immediately.

- 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 generally occurs with a delayed healing process and infection, often after a tooth extraction. Contact your doctor and dentist if you experience such symptoms.
- an unusual fracture of the thigh bone may 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 which is sometimes severe.

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

- joint swelling
- 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
- fatigue, swelling of the hands or legs
- Sometimes (may affect up to 1 in 100 people):
- nausea
- vomiting
- irritation or inflammation of the esophagus (oesophagus – the tube that connects your mouth with your stomach) or stomach
- black or tarry stools
- blurred vision, pain or redness in the eye
- rash
- redness of the skin
- transient flu-like symptoms, such as aching muscles and feeling unwell, sometimes with fever, usually at the start of treatment
- taste changes

Rare (may affect up to 1 in 1000 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 (oesophagus - the tube that connects your mouth to your stomach)
- rash that worsens with sunlight
- mouth ulcers if the tablets are chewed or sucked

Very rarely (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 may 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 us obtain more information about the safety of this medicine.

5. How to store this medicine?

- Keep out of the sight and reach of children.
- Do not use this medicine after the expiry date. This can be found on the box and the blister strip after EXP. It includes a month and a year. The last day of that month is the expiry date.
- There are no special storage conditions for this medicine.
- Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not enter the environment.

6. Contents of the pack and other information

What substances are in this medicine?

The active substance in this medicine is alendronic acid (as sodium alendronate). Each tablet contains 10 mg alendronic acid (as sodium alendronate).

The other substances 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 a pack?

Alendronic Acid Accord 10 mg Tablets are available as white to off-white, oval, biconvex tablets with the imprint '10' on one side and no imprint on the other side.

Alendronic Acid 10 mg tablets are available in opaque, white PVC/ALU blister strips with 14, 28, 30, 50, 56, 84, 90, 98, 112, or 140 tablets.

Not all pack sizes may be marketed.

Marketing authorization holder and manufacturer Marketing authorization holder

Accord Healthcare B.V. Winthontlaan 200
3526 KV Utrecht, Netherlands

Manufacturer

Accord Healthcare Polska Sp.z o.o.,
ul. Lutomierska 50, 95-200 Pabianice, Poland

RVG 100473

This medicine is registered in EEA member states under the following names:

Country	Proposed name
Italy :	Alendronato AHCL 10 mg Compresse
Slovenia :	Natrijev Alendronat Accord 10 mg Tablete
Netherlands :	Alendroninezuur Accord 10 mg tablets
United Kingdom :	Alendronic Acid 10 mg Tablets

This leaflet was last approved in January 2025.

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