

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Alendronat ratiopharm Veckotablett 70 mg 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.

What is in this leaflet

1. What Alendronat ratiopharm Veckotablett is and what it is used for
2. What you need to know before you take Alendronat ratiopharm Veckotablett
3. How to take Alendronat ratiopharm Veckotablett
4. Possible side effects
5. How to store Alendronat ratiopharm Veckotablett
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1. What Alendronat ratiopharm Veckotablett is and what it is used for

What Alendronat ratiopharm Veckotablett is

Alendronat ratiopharm Veckotablett belongs to a group of medicines (called bisphosphonates) that are used in the treatment of bone disorders. The medicine works directly on your bones, making them stronger and thus less likely to break.

The bone is a living tissue, i.e. the body is continuously breaking down old bone tissue in the skeleton and replacing it with new tissue. In women after the menopause, bone loss (postmenopausal osteoporosis) can occur. The bones become thinner and more brittle and are more likely to break following a fall or a sprain.

What Alendronat ratiopharm Veckotablett is used for

Alendronat ratiopharm Veckotablett is used in the treatment of bone loss (osteoporosis) in women after the menopause, in order to reduce the risk of spinal and hip fractures.

2. What you need to know before you take Alendronat ratiopharm Veckotablett

Do NOT take Alendronat ratiopharm Veckotablett

- if you are allergic to alendronic acid or any of the other ingredients of this medicine (listed in section 6);
- if you suffer from a disorder of the gullet (the tube which connects your mouth with your stomach, sometimes known as the oesophagus) or any other factors which prolong emptying of the gullet, such as severe narrowing of the gullet or failure to relax the gullet muscles (achalasia);
- if you cannot stand or sit upright for at least 30 minutes;
- if you have low blood calcium (hypocalcaemia).

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 Alendronat ratiopharm Veckotablett

- if you suffer from gastrointestinal disorders, such as difficulty swallowing, disorders of the gullet, inflammation or ulcers of the stomach lining or duodenum;
- if you have suffered from a severe gastrointestinal disorder within the last year. This includes stomach ulcers, gastrointestinal bleeding or any surgical procedures in the upper gastrointestinal tract;
- 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 have an abnormal bone or mineral metabolism (e.g. vitamin D deficiency, reduced calcium absorption, problems with parathyroid hormones) that can lead to low blood calcium;
- if you are taking certain other medicines (glucocorticoids, cortisone products);
- if you have cancer;
- if you are undergoing chemotherapy or radiotherapy;
- if you have inadequate dental hygiene;
- if you suffer from periodontal disease;
- if you smoke;
- if you are undergoing dental treatment or if a dental procedure is planned, please tell your dentist that you are taking Alendronat ratiopharm Veckotablett;
- if you have renal problems.

It is important to tell your doctor before taking Alendronat ratiopharm Veckotablett if any of these apply to you.

Precautions:

During therapy, you should take care of good oral hygiene and receive regular dental check-ups. Contact your doctor if you notice symptoms such as dental mobility, pain, or swelling.

Children and adolescents

Alendronat ratiopharm Veckotablett should not be given to children and adolescents.

Other medicines and Alendronat ratiopharm Veckotablett

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

Alendronat ratiopharm Veckotablett may **not** be taken together with calcium products, medicines that bind stomach acid (antacids) or any other medicines, as this impairs absorption of alendronic acid. You may not take these medicines until **at least 30 minutes** after intake of Alendronat ratiopharm Veckotablett.

Particular caution is required when taking Alendronat ratiopharm Veckotablett with anti-inflammatory and analgesic medicines from the non-steroidal anti-inflammatory drug group (NSAIDs) as gastrointestinal side effects could occur more often.

Alendronat ratiopharm Veckotablett with food and drink

Alendronat ratiopharm Veckotablett may **not** be taken together with food or beverages (including mineral water). You may not take food or beverages (including mineral water) until **at least 30 minutes** after intake of Alendronat ratiopharm Veckotablett.

Pregnancy and breast-feeding

You should not take Alendronat ratiopharm Veckotablett if you are pregnant or breast-feeding.

Driving and using machines

Alendronat ratiopharm Veckotablett can induce side effects such as dizziness, vertigo or blurred vision. As a result your capacity to react may be altered and your ability to drive and use machines can be impaired.

Alendronat ratiopharm Veckotablett contains lactose

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

3. How to take Alendronat ratiopharm Veckotablett

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

What the recommended dose is

Take **1 tablet once a week, always on the same day of the week**. Choose the day of the week that best fits your schedule.

Your doctor will decide how long your treatment will last.

Patients with impaired kidney function

No dose adjustment is necessary in patients with mild to moderately impaired kidney function. Alendronat ratiopharm Veckotablett is not recommended in patients with severely impaired kidney function.

Your doctor will tell you if you need to take additional calcium and vitamin D. This may be necessary if intake from your daily diet is insufficient.

Instructions for intake of Alendronat ratiopharm Veckotablett

Please follow closely the instructions below, in order to help the tablet to reach your stomach and to reduce any possible irritation of the gullet. These instructions are also to ensure that Alendronat ratiopharm Veckotablett works properly.

- **After getting up for the day and before eating or drinking anything**, swallow the tablet whole with a full **glass of water** (not less than 200 ml);
- Take your tablet with tap water only and not with mineral water or any other beverages;
- **You must swallow the tablet whole**. Due to the risk of ulceration of the mouth and throat, do not crush or chew the tablet or allow it to dissolve in your mouth;
- **Do not lie down again for at least 30 minutes after taking** the tablet. You must remain fully upright (either sitting, standing or walking);
- Do not **eat**, drink or take any other medicines for **at least 30 minutes after taking** the tablet;
- Do not lie down again until you have eaten something;
- Do not take the tablet at bedtime or before getting up for the day.

Please follow these instructions; otherwise the risk of side effects in the gullet can increase (see also section 4).

If you take more Alendronat ratiopharm Veckotablett than you should

If you have taken too many tablets at once, drink a full glass of milk and tell your doctor **immediately!** Do not try to make yourself vomit and do not lie down. Try to remain completely upright. The following may be signs of overdose:

- muscle or abdominal cramps; or
- gastrointestinal complaints, such as heartburn.

If you forget to take Alendronat ratiopharm Veckotablett

If you forget to take one tablet at the correct time, take it on the morning after you remember. Return to taking one tablet, as originally scheduled on your chosen day of the week. Do not take a double dose if you have forgotten to take the previous dose for a week or longer.

If you stop taking Alendronat ratiopharm Veckotablett

Osteoporosis therapy is usually a long-term treatment. Your osteoporosis can only be treated with Alendronat ratiopharm Veckotablett if you take it regularly. Ask your doctor, therefore, if you want to break off your treatment.

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.

Important side effects:

- Severe allergic reactions with swelling of the face and breathlessness have been reported. If you feel that you have experienced such a reaction, you must seek medical help **immediately**.
- Severe skin reactions with redness and blistering or other effects on the skin or mucous membranes have been reported (signs of exfoliative dermatitis, Stevens-Johnson syndrome and Lyell's disease). If you feel that you have experienced such a reaction, you must seek medical help **immediately**.
- If signs of a disorder of the gullet occur, such as difficulty or pain on swallowing, pain behind the breast bone, or new or worsening heartburn, you should stop taking Alendronat ratiopharm Veckotablett and talk to a doctor (see also "Warnings and precautions"). These symptoms are particularly likely to occur if you do not take the tablets exactly as described in the section "Instructions for intake of Alendronat ratiopharm Veckotablett". If you continue taking Alendronat ratiopharm Veckotablett after such symptoms have occurred, these side effects can worsen.

The following side effects have been observed:Very common (may affect more than 1 in 10 people)

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

Common (may affect 1 to 10 people in 100)

- headache, dizziness;
- vertigo;
- abdominal pain, indigestion, constipation, diarrhoea, flatulence, ulceration of the gullet, swallowing difficulties, a bloated feeling, acidic belching;
- hair loss, itching of the skin;
- joint swelling;
- feeling of weakness, swelling in the arms or legs (oedema).

Uncommon (may affect 1 to 10 people in 1,000)

- changed sense of taste;
- inflammation of the eye (uveitis, scleritis, episcleritis);
- nausea, vomiting, inflammation of the stomach lining, inflammation of the gullet, tissue defects (erosions) in the gullet, black stool and/or stool containing blood;
- skin rash, inflammatory skin redness;
- transient flu-like symptoms (muscle pain, feeling unwell and, rarely, fever) usually at the beginning of treatment.

Rare (may affect 1 to 10 people in 10,000)

- hypersensitivity reactions (including nettle rash and swelling of the face, lips, tongue and/or throat);
- low blood calcium levels with symptoms such as muscle cramps or twitching, tingling of the fingers or around the mouth (symptomatic hypocalcaemia), mostly in predisposed patients;
- severe narrowing of the gullet, ulceration of the mouth and throat, simultaneous occurrence of perforation, ulceration, bleeding in the upper gastrointestinal region (signs may be severe pain in the upper abdomen, vomit containing blood, and black stool);
- rash with sensitivity to light; severe skin reactions, sometimes with redness and blister formation (including Stevens-Johnson syndrome and toxic epidermal necrolysis);
- death of bone tissue of the jaw (osteonecrosis). Contact your doctor if you notice symptoms such as dental mobility, pain, or swelling;
- 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.

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

Do not store above 25 °C.

Store in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater. 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 ratiopharm Veckotablett contains

- The active substance is alendronic acid. Each tablet contains 70 mg alendronic acid (as alendronate sodium trihydrate).
- The other ingredients are: microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, magnesium stearate (Ph.Eur.).

What Alendronat ratiopharm Veckotablett looks like and contents of the pack

Alendronat ratiopharm Veckotablett is a white to pale white tablet marked with “AN 70” on one side and with an arrow on the other side. Alendronat ratiopharm Veckotablett is available in packs containing 2, 4, 8, 12 and 40 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

<To be completed nationally>

Manufacturer

<To be completed nationally>

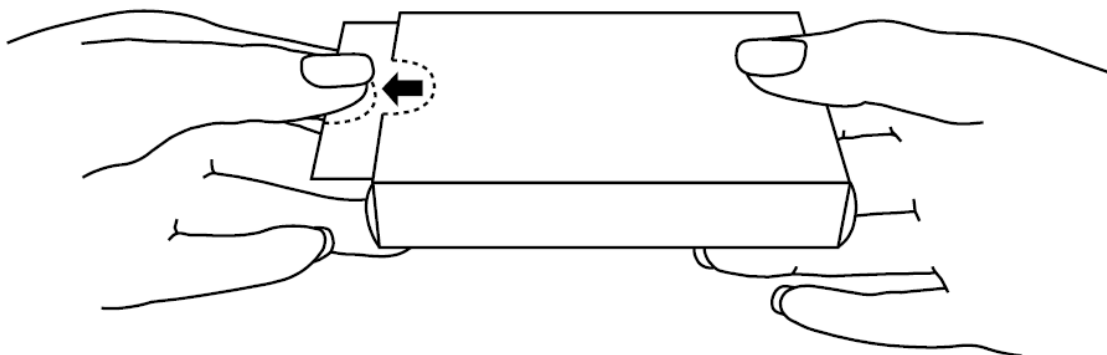
This medicinal product is authorised in the Member States of the European Economic Association (EEA) under the following names:

Austria:	Alendronsäure "ratiopharm" 70 mg - einmal wöchentlich Tabletten
Germany:	Alendronsäure-ratiopharm 70 mg Tabletten
Italy:	Alendronato ratiopharm 70 mg compresse
Luxembourg:	Alendronsäure-ratiopharm 70 mg Tabletten
Portugal:	Ácido Alendrónico refta 70 mg comprimidos
Sweden:	Alendronat ratiopharm Veckotablett 70 mg tablett

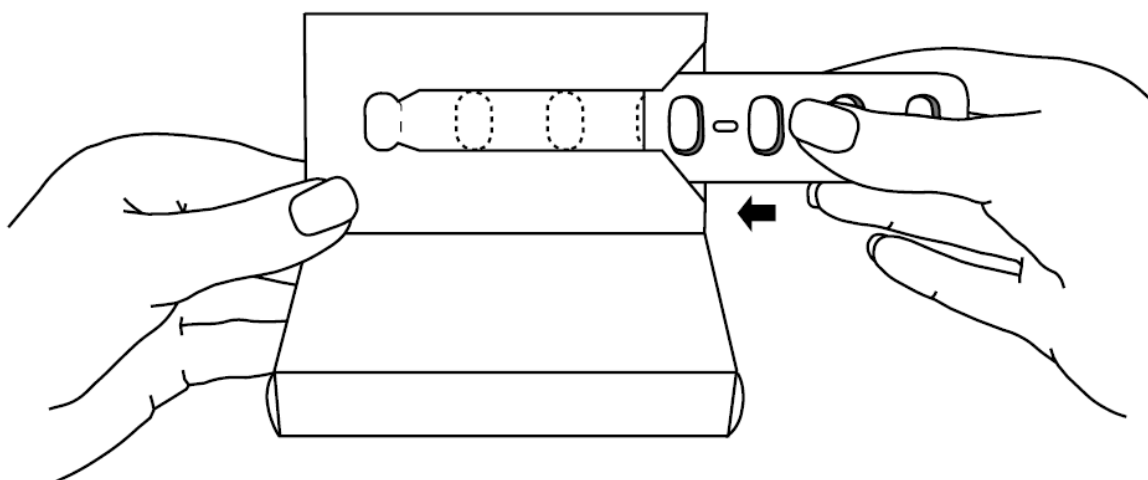
This leaflet was last approved in 8 November 2018

FURTHER DETAILS**The following information shows you how to use the pack correctly:**

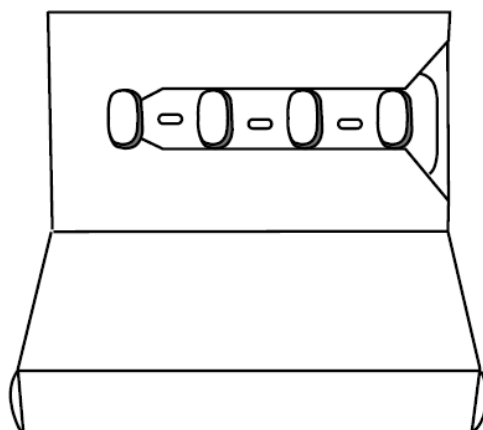
1. Using your thumb, press and break off the perforation of the outer carton. Pull out the intake recommendation with a sharp tug.



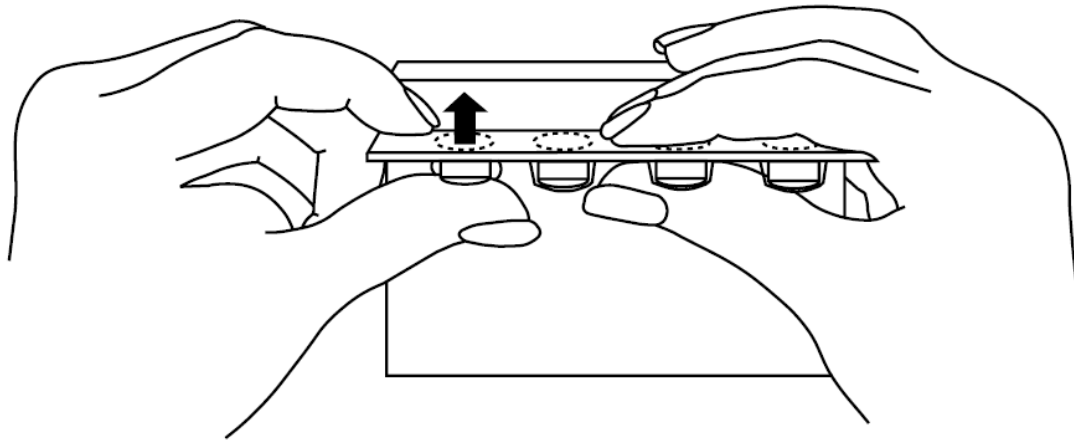
2. Remove the blister pack with the tablets from the outer carton.
3. Push the blister pack with the tablets into the slot in the flap.



4. After opening the outer carton and carefully reading the Package Leaflet, choose a day of the week on which you will always take your tablet. As a reminder, enter the day of the week which best fits your schedule in the space provided on the flap of the outer carton. Also enter the date you intend to take the tablet in the appropriate spaces under the tablets.



5. There are 4 stickers on the front of the outer carton. As a reminder, you can attach these stickers to your calendar on the day of the week you have selected for taking your tablet. If you have a pack with 12 tablets, there are a further 8 stickers on the back of the intake recommendation. You can also attach these stickers to your calendar on the days you have selected for taking your tablet.
6. When removing the tablet, push it from below through the pre-punched perforation in the flap of the outer carton.



7. If you have a pack with 12 tablets, you must remove the blister pack from the flap after you have taken the last tablet. Then push a new blister pack of tablets into the slot in the flap.

