

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking FONAT?

FONAT contains the active ingredient alendronate sodium. FONAT is used to treat osteoporosis. For more information, see Section [1. Why am I taking FONAT?](#) in the full CMI.

2. What should I know before I take FONAT?

Do not take if you have ever had an allergic reaction to FONAT or any of the ingredients listed at the end of the CMI. Do not take FONAT if you have the following medical conditions: certain disorders of the food pipe, conditions that cause swallowing difficulty, unable to stand or sit upright for at least 30 minutes, low blood calcium. **Talk to your doctor if you have other medical conditions, take other medicines, have dental or jaw bone problems or planning dental surgery, pregnant or breastfeeding or plan to become pregnant or breastfeed.** See Section [2. What should I know before I take FONAT?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with FONAT and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take FONAT?

- Swallow whole one tablet with a full glass of plain water, once per week. Do not chew or suck on the tablet.

Take in the morning after getting up, do not take at bedtime. Stay upright (sitting or standing) for at least 30 minutes after swallowing. Do not eat, drink (other than plain water), or take other medications during this time.

More instructions can be found in Section [4. How do I take FONAT?](#) in the full CMI.

5. What should I know while taking FONAT?

Things you should do	- Remind any doctor, dentist or pharmacist you visit that you are taking FONAT. - Stop taking FONAT and call your doctor if you develop pain or difficulty swallowing, chest pain, or new or worsening heartburn, or if you become pregnant. - Tell your doctor immediately if you develop new or unusual hip, thigh, bone, muscle or joint pain, or if you break a bone.
Things you should not do	- Do not give FONAT to anyone else, even if they have the same condition as you. - Do not stop taking your medicine, or change the dosage, without first checking with your doctor.
Driving or using machines	Be careful driving or operating machinery until you know how FONAT affects you.
Drinking alcohol	Tell your doctor if you drink alcohol: your doctor may suggest drinking less.
Looking after your medicine	Keep FONAT in a cool, dry place, away from light and moisture where the temperature stays below 25°C. Keep the tablets in the blister pack until it's time to take them.

For more information, see Section [5. What should I know while taking FONAT?](#) in the full CMI.

6. Are there any side effects?

Less serious side effects: stomach pain, gas; heartburn; nausea, vomiting; constipation, diarrhoea; headache; unusual tiredness; muscle, joint, bone aches (rarely may be severe); flu-like symptoms; joint swelling; dizziness or spinning sensation; swelling of hands, ankles or feet; hair loss; changes in sense of taste. **Serious side effects:** skin rash or itchiness; mouth ulcers; blurred vision, eye pain or redness; jaw or dental problems; new or unusual pain in hips or thigh, tingling sensation in the fingers or around the mouth, difficulty or pain upon swallowing, chest pain; new or worsening heartburn; swelling of the face, lips, mouth, throat or tongue causing difficulty in breathing; pinkish, itchy swellings on the skin, severe skin reactions; black tar-like and/or bloody stools. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Consumer Medicine Information (CMI)

This leaflet provides important information about taking FONAT. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking FONAT.**

Where to find information in this leaflet:

1. [Why am I taking FONAT?](#)
2. [What should I know before I take FONAT?](#)
3. [What if I am taking other medicines?](#)
4. [How do I take FONAT?](#)
5. [What should I know while taking FONAT?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I taking FONAT?

FONAT contains the active ingredient alendronate sodium. FONAT belongs to a group of nonhormonal medicines called bisphosphonates.

FONAT is used to treat osteoporosis. This condition is caused by changes in the way bone is normally maintained.

FONAT works by slowing down the process of old bone being removed, which allows the bone-forming cells time to rebuild normal bone. FONAT not only helps prevent the loss of bone but actually helps to rebuild bone and makes bone less likely to fracture. Thus, FONAT prevents or reverses the progression of osteoporosis.

FONAT starts working on the bone cells immediately, but measurable effects on bone mass may not be seen for several months or more.

Understanding bone

Bone is living, growing tissue. Throughout life, our bodies are breaking down old bone and rebuilding new bone in a continuous cycle. Until our late 20s, while bones are still developing, we gain bone by building more than we lose. From then until about age 35 the process is usually in balance, so that the amount of bone lost is about equal to the amount that is replaced. This balanced process keeps your skeleton healthy and strong. After about age 35 this balance is disturbed, with bone loss occurring at a slightly faster rate than it can be replaced. In women, after menopause, hormonal changes cause bone loss at an even faster rate. When bone loss is excessive, bones can become thinner and weaker, and therefore are more likely to break.

Osteoporosis

"Osteo" means bone, and "porosis" means something that has holes in it, like a sponge. Therefore, osteoporosis is a disease which causes bones to become more porous, gradually making them weaker, more brittle and likely to break.

Osteoporosis is common in postmenopausal women. The menopause occurs when the ovaries virtually stop producing the female hormone, oestrogen, or are removed (which may occur, for example, at the time of a hysterectomy). At this time, bone is removed faster than it is formed, so bone loss occurs and bones become weaker. The earlier a woman reaches the menopause, the greater the risk of osteoporosis.

Osteoporosis also occurs in men but is less common than in women.

Osteoporosis can also occur in people receiving corticosteroid medicines. If taken in high doses or for a long period of time, corticosteroid medicines can cause bone to be removed faster than it is formed. This causes loss of bone and therefore, bones become weaker and are more likely to break.

Maintaining bone mass and preventing further bone loss are important to keep your skeleton healthy.

Early on, osteoporosis usually has no symptoms. However, if left untreated it can result in broken bones, also called fractures.

Although fractures usually cause pain, fractures of the bones of the spine may go unnoticed until they cause height loss. Fractures may occur during normal, everyday activity, such as lifting, or from minor injury that would not ordinarily fracture normal bone.

Fractures usually occur at the hip, spine, or wrist and can lead not only to pain, but also to considerable deformity and disability, such as stooped posture from curvature of the spine, and loss of mobility.

Ask your doctor if you have any questions about why FONAT has been prescribed for you.

Your doctor may have prescribed FONAT for another reason.

FONAT is not addictive.

2. What should I know before I take FONAT?

Warnings

Do not take FONAT if:

- you are allergic to alendronate sodium, or any of the ingredients listed at the end of this leaflet.
Always check the ingredients to make sure you can take this medicine.
- you have certain disorders of the food pipe (oesophagus) including those that cause difficulty in swallowing
- you are unable to stand or sit upright for at least 30 minutes
- your doctor has told you that you currently have low blood calcium

- your dentist advises you to consult your doctor first
- the expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking FONAT, talk to your doctor.

Check with your doctor if you:

- have any other medical conditions especially the following:
 - kidney disease
 - swallowing or digestive problems, such as ulcers
- take any medicines for any other condition
- have any allergies to any other medicines, foods, preservatives or dyes
- have dental or jaw-bone problems or are planning to have a course of dental surgery
- currently smoke or have been a smoker in the past.

If you have not told your doctor about any of the above, tell him/ her before you start taking FONAT.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Irritation of the food pipe (oesophagus)

You should know that in some people, FONAT can irritate or burn the food pipe (also called oesophagus). The chances of this happening should be reduced when you follow the instructions in section [4. How do I take FONAT?](#)

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not take FONAT if you are pregnant or breastfeeding.

FONAT has not been studied in pregnant or breastfeeding women.

Talk to your doctor if you are pregnant or breastfeeding or plan to become pregnant or breastfeed.

Children

Do not give FONAT to a child.

FONAT has not been studied in children.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with FONAT and affect how it works. These include:

- antacids, medicines used to treat indigestion
- calcium supplements

- vitamins

You may need different amounts of your medicines, or you may need to take different medicines.

Therefore, take FONAT at least 30 minutes before taking any of these or other medicines to make sure there is no problem with absorption.

You can take aspirin while you are being treated with FONAT. However, both aspirin and FONAT may increase the chance of stomach upsets.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking FONAT.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect FONAT.

4. How do I take FONAT?

How much to take

- **Take FONAT only when prescribed by your doctor.**
- The usual dose of FONAT is one 70 mg tablet once a week.

When to take FONAT

- Choose the day of the week that best fits your schedule. Every week, take one table of FONAT on your chosen day.

How to take FONAT

- **Take FONAT after getting up for the day. Do not take it at bedtime.**
- **Swallow one tablet whole with a full glass of plain water only.**

Do not take any food, medicines or drinks other than plain water with your FONAT. It is important to take FONAT with plain water only, not mineral water.

Food, other drugs, mineral water and other drinks, including fruit juices, coffee and tea, will reduce the effect of FONAT by interfering with the absorption into the body.

- **Stay upright for at least 30 minutes after swallowing FONAT and do not take any food, medicines or drinks other than plain water during this time.**
- **Do not lie down immediately after swallowing it.**

It is important to stay upright (sitting, standing or walking around) for at least 30 minutes after swallowing your tablet.

It is also very important to stay upright until after you have eaten your first food of the day.

These actions will help make sure your tablet reaches your stomach quickly and help reduce the potential burn or irritation to your food pipe (oesophagus).

FONAT is effective only if taken when your stomach is empty. Food, drinks other than plain water, and other medicines will lessen the effect of FONAT by interfering with its absorption into the body.

- **Do not chew or suck on a tablet of FONAT.**

Mouth ulcers may occur if the tablet is chewed or dissolved in the mouth.

How long to take FONAT

- It is important that you continue taking FONAT for as long as your doctor prescribes.

FONAT can only treat your osteoporosis, by helping prevent further loss of bone and continuing to rebuild bone, if you take it every week.

If you forget to take FONAT

Skip the tablet you missed and take one tablet the following morning after you remember.

If you take the missed FONAT tablet after you have eaten or had a drink, it may not work as well as it should.

Therefore, it is better to skip the missed tablet and continue with your regular schedule on your chosen day.

If you are not sure about what to do, talk to your doctor or pharmacist.

Do not take two tablets on the same day to make up for the dose that you missed.

If you have trouble remembering to take your FONAT, ask your pharmacist for some hints.

If you take too much FONAT

If you take too many tablets at one time, drink a full glass of milk. Do not induce vomiting. Do not lie down.

If you think that you or anyone else has taken too much FONAT, urgent medical attention maybe needed.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking FONAT?

Things you should do

- Tell your doctor and pharmacist that you are taking FONAT, if you are about to be started on any new medicine.
- Tell your dentist that you are taking FONAT, if you develop a toothache or require a dental procedure.
- Tell your doctor, if you develop new or unusual pain in your leg.

Rarely, patients have experienced fracture in a specific part of the thigh bone.

- Make sure you have an adequate intake of calcium in your diet.

Your doctor, dietician or pharmacist can tell you what foods you should eat.

- Visit your doctor regularly so they can check on your progress.

Call your doctor straight away if you:

- develop difficulty or pain upon swallowing, chest pain, or new or worsening heartburn and stop taking FONAT
- become pregnant while taking FONAT and stop taking the tablets.

Remind any doctor, dentist or pharmacist you visit that you are taking FONAT.

Things you should not do

- Do not give FONAT to anyone else, even if they have the same condition as you.

Things that would be helpful for your osteoporosis

Some self-help measures suggested below may help your osteoporosis.

Talk to your doctor or pharmacist about these measures and for more information.

- Exercise - can be helpful in building and maintaining strong bones. Regular exercise such as a brisk walk is a good idea. Talk to your doctor before you begin any exercise program.
- Diet - eat a balanced diet. You may need to increase the amount of calcium in your diet by eating calcium-rich foods or taking a calcium supplement. Your doctor will advise you.
- Smoking - appears to increase the rate at which you lose bone and, therefore, may increase your risk of fracture. Your doctor may ask you to stop smoking or at least cut down.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how FONAT affects you.

There have been side effects reported with alendronate that may affect your ability to drive or operate machinery. Individual responses to alendronate may vary. (See [6. Are there any side effects?](#))

Drinking alcohol

Tell your doctor if you drink alcohol.

If you drink excessively on a regular basis, you may increase your risk of developing osteoporosis. Your doctor may advise you to cut down the amount of alcohol you drink.

Looking after your medicine

- Keep your tablets in the blister pack until it is time to take them.

If you take the tablets out of the blister pack they may not keep well.

- Keep FONAT below 25°C.
- Do not freeze the product.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Less serious side effects

Less serious side effects	What to do
Stomach related: • stomach pain, gas in the stomach or bowel, wind • an uncomfortable feeling in the stomach or belching (burping) after eating, also called dyspepsia, or heartburn • feeling sick (nausea), vomiting • constipation, diarrhoea Head and nervous system-related: • headache • dizziness or spinning sensation • changes in sense of taste • hair loss Muscle and skeleton related: • aching muscles, joints and/or bones, which rarely can be severe • swelling of joints General: • unusual tiredness or weakness	Speak to your doctor if you have any of these less serious side effects and they worry you. Most of these are the more common side effects of FONAT and for the most part, these have been mild.

Less serious side effects	What to do
• flu-like symptoms typically at the start of treatment, such as aching muscles, generally feeling unwell and rarely fever • swelling of hands, ankles or feet	

Serious side effects

Serious side effects	What to do
Skin-related: • skin rash or redness of the skin, sometimes made worse by sunlight, itchiness Gastrointestinal-related: • mouth ulcers Eye/ear-related: • blurred vision, pain or redness in the eye Muscle/skeleton-related: • new or unusual pain in your hip or thigh General conditions: • symptoms of low blood calcium levels including muscle cramps or spasms or tingling sensation in the fingers or around the mouth	Tell your doctor immediately if you notice any of these serious side effects.
Muscle/skeleton-related: • Jaw-bone or dental problems (including toothache). Jaw-bone problems may include infection, and delayed healing after a tooth extraction or other work that involves drilling into the jawbone	Tell your dentist and doctor immediately if you notice any of these serious side effects.
Gastrointestinal-related: • difficulty or pain upon swallowing • chest pain • new or worsening heartburn These side effects may be due to irritation or ulceration of the food pipe. They may worsen if you continue taking the tablets.	If any of these happen, stop taking FONAT and tell your doctor immediately.

Very serious side effects

Very serious side effects	What to do
Allergic reaction: • swelling of the face, lips, mouth, throat or tongue which may cause	Call your doctor straight away, or go straight to the Emergency

Very serious side effects	What to do
difficulty in breathing or swallowing - pinkish, itchy swellings on the skin, also called hives or nettle rash If you have the swelling described above, you may be having a serious allergic reaction to FONAT. Skin-related: - severe skin reactions Gastrointestinal-related: - black tar-like and/or bloody stools - rarely, stomach or duodenal ulcers (some severe) have occurred, but it is not known whether these were caused by FONAT.	Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What FONAT contains

Active ingredient (main ingredient)	alendronate sodium 70 mg
Other ingredients (inactive ingredients)	lactose monohydrate microcrystalline cellulose povidone croscarmellose sodium magnesium stearate
Potential allergens	sulfites sugars as lactose.

Do not take this medicine if you are allergic to any of these ingredients.

What FONAT looks like

FONAT is a white bi-convex tablet, debossed "AD70" on one side and "G" on the reverse (AUST R 134702).

FONAT is available in a blister pack containing 4 tablets

Who distributes FONAT

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

This leaflet was prepared in December 2025.

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