

Package leaflet: Information for the user

Romax Once Weekly 70mg Tablets Alendronic Acid (as sodium alendronate)

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

1. What Romax Once Weekly is and what it is used for

The name of your medicine is Romax Once Weekly 70 mg tablets (referred to as alendronic acid throughout this leaflet). Romax Once Weekly is a tablet containing the active substance Alendronic acid (commonly called alendronate) and belongs to a group of non-hormonal medicines known as bisphosphonates.

Alendronic acid 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 Romax Once Weekly used for?

Your doctor has prescribed Romax Once Weekly to treat your osteoporosis. Romax Once Weekly reduces the risk of spine and hip fractures.

Romax Once Weekly is a once weekly treatment.

What is osteoporosis?

Osteoporosis is a thinning and weakening of 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?

As well as your treatment with Romax Once Weekly, 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 Romax Once Weekly

Do not take Romax Once Weekly:

- 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 or pharmacist before taking Romax Once Weekly :

It is important to tell your doctor before taking Romax Once Weekly if:

- you suffer from kidney problems,
- you have any swallowing or digestive problems
- your doctor has told you that you have Barrett's oesophagus (a condition associated with change in the cells that line the lower oesophagus)
- you have been told you have low blood calcium,
- you have poor dental health, gum disease, a planned dental extraction or you don't receive routine dental care,
- you have cancer,
- you are undergoing chemotherapy or radiotherapy,
- you are taking angiogenesis inhibitors (such as bevacizumab, or thalidomide), which are used in the treatment of cancer,
- you are taking corticosteroids (such as prednisone or dexamethasone) which are used in the treatment of such conditions as asthma, rheumatoid arthritis, and severe allergies,
- 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 Romax Once Weekly.

It is important to maintain good oral hygiene when being treated with Romax Once Weekly. 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 less than 30 minutes after taking Romax Once Weekly. These side effects may worsen if patients continue to take Romax Once Weekly after developing these symptoms.

Children and adolescents

Romax Once Weekly should not be given to children and adolescents less than 18 years of age.

Other medicines and Romax Once Weekly

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 Romax Once Weekly if taken at the same time. Therefore, it is important that you follow the advice given in section 3 How to take Romax Once Weekly.

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 Romax Once Weekly.

Romax Once Weekly with food and drink

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

Pregnancy and breast-feeding and fertility

Romax Once Weekly is only intended for use in postmenopausal women. You should not take alendronic acid if you are or think you may be pregnant or if you are breast-feeding.

Driving and using machines

There have been side effects (including blurred vision, dizziness and severe bone, muscle or joint pain) reported with Romax Once Weekly that may affect your ability to drive or operate machinery. Individual responses to Romax Once Weekly may vary. (See section 4)

Sodium:

Romax Once Weekly contains sodium which is less than 1 mmol (23 mg) of sodium per tablet, that is to say essentially 'sodium-free.'

3. How to take Romax Once Weekly

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

Take one Romax Once Weekly tablet once a week.

- 1) Choose one day of the week that best fits your schedule. Every week, take one Romax Once Weekly tablet on your chosen day.

It is important to follow the instructions 2), 3), 4) and 5) to help Romax Once Weekly tablet 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 Romax Once Weekly tablet whole with a full glass of water only (not mineral water) (not less than 200 ml)
 - Do not take with mineral water (still or sparkling).
 - Do not take with coffee or tea.
 - Do not take with juice or milk.

Do not crush or chew the tablet or allow it to dissolve in your mouth.

- 3) 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 food of the day.
- 4) Do not take Romax Once Weekly at bedtime or before getting up for the day.
- 5) If you develop difficulty or pain upon swallowing, chest pain, or new or worsening heartburn, stop taking Romax Once Weekly and contact your doctor.
- 6) After swallowing your Romax Once Weekly tablet, wait at least 30 minutes before taking your first food, drink, or other medicine of the day, including antacids, calcium supplements and vitamins. Romax Once Weekly is effective only if taken when your stomach is empty.

If you take more Romax Once Weekly than you should

If you take too many tablets, 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 Romax Once Weekly

If you miss a dose, just take one tablet in the morning after you remember. 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 Romax Once Weekly

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

An Instruction Card is included in the carton for Romax Once Weekly. It contains important information reminding you how to take Romax Once Weekly properly.

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,
- 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 healing and infection, often following tooth extraction. Contact your doctor and dentist if you experience such symptoms
- 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.
- bone, muscle and/or joint pain which is severe.

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; uncomfortable feeling in the stomach or belching after eating; constipation; full or bloated feeling in the stomach; diarrhoea; flatulence,
- hair loss; itching,
- headache; dizziness,
- 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,
- blurred vision; pain or redness in the eye,
- 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.

Rare (may affect up to 1 in 1000 people):

- symptoms of low blood calcium levels including muscle cramps or spasms and/or tingling sensation in the fingers or around the mouth,
- stomach or peptic ulcers (sometimes severe or with bleeding),
- narrowing of the gullet (oesophagus – the tube that connects your mouth with your stomach),

- rash made worse by sunlight,
- mouth ulcers when the tablets have been chewed or sucked.

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

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail:

medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Romax Once Weekly

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

Do not use Romax Once Weekly after the expiry date which is stated on the carton after EXP. The expiry date 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 Romax Once Weekly contains

- The active substance is alendronic acid. Each film-coated tablet contains 70 mg alendronic acid (as sodium alendronate).
- The other ingredients are: Microcrystalline cellulose, maize starch, sodium starch glycolate (Type A), povidone (K- 30) and magnesium stearate.

What Romax Once Weekly looks like and contents of the pack

White to off-white, oval, biconvex, uncoated tablets debossed with 'F' on one side and '21' on the other side.

They are supplied in blister packs of 2, 4, 8, 12, 20, 30, 40, 50 or 60 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Aurobindo Pharma (Malta) Limited
Vault 14, Level 2, Valletta Waterfront
Floriana FRN 1913
Malta

Manufacturer:

APL Swift Services (Malta) Limited
HF26, Hal Far Industrial Estate, Hal Far
Birzebbugia, BBG 3000
Malta

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