

Romax Once Weekly 70 mg Tablets

Alendronic acid

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What is Romax Once Weekly 70 mg Tablets and what it is used for
2. Before you take Romax Once Weekly 70 mg Tablets
3. How to take Romax Once Weekly 70 mg Tablets
4. Possible side effects
5. How to store Romax Once Weekly 70 mg Tablets
6. Further information

1. WHAT IS ROMAX ONCE WEEKLY 70 MG TABLETS AND WHAT IT IS USED FOR

Alendronate belongs to a group of non-hormonal medicines called bisphosphonates. Alendronate 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.

Your doctor has prescribed Romax Once Weekly 70 mg Tablets to treat your **osteoporosis**. Romax Once Weekly 70 mg Tablets has been shown to **reduce the risk of spine and hip fractures**.

Romax Once Weekly 70 mg Tablets is a **once weekly** treatment.

Osteoporosis is a thinning and weakening of the 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.

As well as your treatment with Romax Once Weekly 70 mg Tablets, 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.

2. BEFORE YOU TAKE ROMAX ONCE WEEKLY 70 MG TABLETS

Do not take Romax Once Weekly 70 mg Tablets

- if you are allergic (**hypersensitive**) to alendronate sodium trihydrate or any of the other ingredients of Romax Once Weekly 70 mg Tablets
- 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.

Take special care with Romax Once Weekly 70 mg Tablets

Tell your doctor before taking Romax Once Weekly 70 mg Tablets

- if you suffer from **kidney problems**
- if you have any **swallowing or digestive problems**
- if your doctor has told you that you have **Barrett's oesophagus** (a condition associated with changes in the cells that line the lower gullet)
- if you have **low blood calcium** levels
- if you have **gum disease, planned dental extraction, poor dental health or you don't receive routine dental care**
- if you have cancer
- if you are undergoing chemotherapy or radiotherapy
- if you are taking steroids (such as prednisone or dexamethasone)
- if you smoke

It is important to maintain good oral hygiene when being treated with **Romax Once Weekly 70 mg Tablets**

You may be advised to have a dental check-up before starting treatment with **Romax Once Weekly 70 mg Tablets**.

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 70 mg Tablets. These side effects may worsen if patients continue to take Romax Once Weekly 70 mg Tablets after developing these symptoms.

Romax Once Weekly 70 mg Tablets should not be given to children and adolescents.

Taking other medicines

It is likely that **calcium supplements, antacids** and **some oral medicines** will interfere with the absorption of Romax Once Weekly 70 mg Tablets 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 70 mg Tablets".

Certain medicines for rheumatism or long-term pain called NSAIDs (e. g. aspirin or ibuprofen) might cause digestive problems. Therefore, caution should be used when these medicines are taken at the same time as Romax Once Weekly 70 mg Tablets.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking Romax Once Weekly 70 mg Tablets with food and drink

It is likely that food and beverages (including mineral water) will make Romax Once Weekly 70 mg Tablets 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 70 mg Tablets".

Pregnancy and breast-feeding

You should not take Romax Once Weekly 70 mg Tablets if you are or think you may be pregnant. Romax Once Weekly 70 mg Tablets is only intended for use in postmenopausal women.

You should not take Romax Once Weekly 70 mg Tablets if you are breast-feeding. Romax Once Weekly 70 mg Tablets is only intended for use in postmenopausal women.

Driving and using machines

Certain side effects (including blurred vision, dizziness and severe bone, muscle and/or joint pain) have been reported during treatment with alendronate which may impair your ability to drive or use machines. The reaction to alendronate may differ from individual to individual (see section 4. "Possible side effects").

Important information about some of the ingredients of Romax Once Weekly 70 mg Tablets

Romax Once Weekly 70 mg Tablets contains lactose. If you have been told by your doctor that you have an intolerance to some sugars (for example lactose), contact your doctor before taking this medicine.

3. HOW TO TAKE ROMAX ONCE WEEKLY 70 MG TABLETS

Always take Romax Once Weekly 70 mg Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Take one 70 mg tablet once a week.

Follow these instructions carefully to make sure you will benefit from Romax Once Weekly 70 mg Tablets.

- 1) Choose the day of the week that best fits your schedule. Every week, take one Romax Once Weekly 70 mg Tablet on your chosen day.

It is very important to follow instructions 2), 3), 4) and 5) to help the Romax Once Weekly 70 mg 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 70 mg Tablet whole **with a full glass of water** only (not mineral water) (not less than 200 ml or 7 fl. oz.).
- Do not take with mineral water (still or sparkling).
 - Do not take with coffee or tea.
 - Do not take with juice or milk.
- 3) Do not chew or crush the tablet or allow it to dissolve in your mouth.
- 4) 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.
- 5) Do not take Romax Once Weekly 70 mg Tablets at bedtime or before getting up for the day.
- 6) If you develop difficulty or pain upon swallowing, chest pain, or new or worsening heartburn, stop taking Romax Once Weekly 70 mg Tablets and contact your doctor.
- 7) After swallowing your Romax Once Weekly 70 mg Tablets, **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 70 mg Tablets is effective only if taken when your stomach is empty.
- 8) It is important that you continue taking Romax Once Weekly 70 mg Tablets for as long as your doctor prescribes the medicine. Romax Once Weekly 70 mg Tablets can treat your osteoporosis only if you continue to take the tablets.

If you take more Romax Once Weekly 70 mg Tablets than you should

If you take too many tablets by mistake, 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 70 mg Tablets

If you miss a dose, just take one tablet on 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 have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Romax Once Weekly 70 mg Tablets can have side effects, although not everybody gets them.

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)

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

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

- narrowing of the gullet (oesophagus - the tube that connects your mouth with your stomach)
- 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,
- mouth ulcers when the tablets have been chewed or sucked
- stomach or peptic ulcers (sometimes severe or with bleeding)
- rash made worse by sunlight
- severe skin reactions (serious illness with blistering of the skin, mouth, eyes and genitals- Stevens-Johnson syndrome and toxic epidermal necrolysis)
- allergic reactions such as hives; swelling of the face, lips, tongue and/or throat, possibly causing difficulty breathing or swallowing
- symptoms of low blood calcium levels including muscle cramps or spasms and/or tingling sensation in the fingers or around the mouth.
- 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.

It will help if you make a note of what you experienced, when it started and how long it lasted.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE ROMAX ONCE WEEKLY 70 MG TABLETS

Keep out of the reach and sight of children.

Do not take the tablets after the expiry date stated on the blister and the carton. 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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Romax Once Weekly 70 mg Tablets contain

The active substance is alendronate sodium trihydrate. Each tablet contains 70 mg alendronic acid as alendronate sodium trihydrate.

The other ingredients are microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, magnesium stearate.

What Romax Once Weekly 70 mg Tablets look like and contents of the pack

Romax Once Weekly 70 mg Tablets are white to off-white, oval tablets, embossed “AN 70” on one side and the Arrow logo on the other.

The tablets are supplied in triplex blister (PVC/PE/PVDC/AL) packs containing 2, 4, 8, 12, 24 and 40 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

Salutas Pharma GmbH, Otto-von-Guericke Allee 1, 39179 Barleben, Germany.

Arrow Generics Limited, Unit 2, Eastman Way, Stevenage, Hertfordshire SG1 4SZ, United Kingdom.

Qualiti (Burnley) Limited, Talbot Street, Briercliffe, Burnley BB102JY, United Kingdom.

Arrow Pharm Limited, HF 62, Hal Far Industrial Estate, Birzebbugia BBG06, Malta.

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium:	Alendronate Sandoz 70 mg tabletten Wekelijks
Czech Republic:	ALENDRONAT SANDOZ 70
France:	ACIDE ALENDRONIQUE SANDOZ 70 mg, comprimé
Germany:	Alendron-HEXAL® einmal wöchentlich 70 mg Tabletten
Greece:	FOROSA
Hungary:	Alendron-HEXAL 70 mg tablets
Ireland:	Romax Once Weekly 70 mg Tablets
Italy:	ALENDRONATO SANDOZ 70 mg compresse
Luxembourg:	Alendronate Sandoz 70 mg comprimés Hebdomadaire
Portugal:	ÁCIDO ALENDRÓNICO Sandoz 70 mg COMPRIMIDOS
Slovak Republic:	Alendronát Sandoz 70 mg 1x týždenne tablety
Spain:	Acido Alendronico Semanal Sandoz 70 mg comprimidos EFG
Sweden:	Alendronat HEXAL Veckotablett

This leaflet was last approved in 04/2014