Alendronic Acid 70mg Oral Solution
Bonasol® 70mg Oral Solution
(sodium alendronate)

Your medicine is known by the above names, but will be referred to as Alendronic Acid oral solution throughout this leaflet.

Patient Information Leaflet

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 Alendronic Acid oral solution is and what it is used for

Alendronic Acid oral solution belongs to a group of non-hormonal medicines called bisphosphonates. Alendronic Acid oral solution is used to
- Prevent the loss of bone (osteoporosis) that occurs in women after they have been through the menopause, and helps to rebuild bone.
- Reduces the risk of spine and hip fractures.

Your doctor has prescribed Alendronic Acid oral solution to treat your osteoporosis and to reduce the risk of spine and hip fractures.

What is osteoporosis?
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.

How can osteoporosis be treated?
Osteoporosis can be treated and it is never too late to begin treatment. Alendronic acid not only prevents the loss of bone but actually helps to rebuild bone you may have lost and reduces the risk of bones breaking in the spine and hip.

As well as your treatment with Alendronic Acid oral solution 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 Alendronic Acid oral solution

Do not take Alendronic Acid oral solution if:
- you are allergic (hypersensitive) to alendronic acid or any ingredients of Alendronic Acid 70mg Oral Solution listed in section 6.
- you have certain problems with your gullet (oesophagus - the tube that connects your mouth with your stomach) such as narrowing or difficulty swallowing liquids
- your doctor has told you that you have low blood calcium
- if you cannot stand or sit upright for at least 30 minutes

If you think any of these apply to you, do not take the solution. Talk to your doctor first and follow the advice given.

Warnings and precautions
Talk to your doctor or pharmacist before taking Alendronic Acid oral solution if:
- you suffer from kidney problems
- you have any allergies
- you have any swallowing or digestive problems
- your doctor has told you that you have Barrett's oesophagus (a condition associated with changes in the cells that line the lower oesophagus)
- you have low blood calcium levels
- you have poor dental health
- you have a planned dental extraction
- you have cancer
- you are undergoing chemotherapy or radiotherapy
- you are taking corticosteroids (such as prednisone or dexamethasone)
- you are taking angiogenesis inhibitors (such as bevacizumab, or thalidomide)
- you don't receive routine dental care
- you have gum disease
- 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 Alendronic Acid oral solution. Appropriate preventive dental care, as recommended by the dentist, should be followed during treatment. 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 lie down after taking Alendronic Acid oral solution. These side effects may worsen if patients continue to take Alendronic Acid oral solution after developing these symptoms.

Children and adolescents
Alendronic Acid oral solution should not be given to children and adolescents under the age of 18 years due to insufficient data on safety and efficacy.

Other medicines and Alendronic Acid oral solution
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medications.
It is likely that calcium supplements, antacids, and some oral medicines will interfere with the absorption of Alendronic Acid oral solution if taken at the same time. Therefore, it is important that you follow the advice given in section 3. HOW TO TAKE ALENDRONIC ACID ORAL SOLUTION.

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 Alendronic Acid oral solution.

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

Alendronic Acid oral solution with food and drink and alcohol
It is likely that food and beverages (including mineral water) will make Alendronic Acid oral solution less effective if taken at the same time. Therefore, it is important that you follow the advice given in section 3. HOW TO TAKE ALENDRONIC ACID ORAL SOLUTION

Pregnancy and breast-feeding
Alendronic Acid oral solution is only intended for use in postmenopausal women.
You should not take Alendronic Acid oral solution if you are or think you may be pregnant, or if you are breast-feeding.
Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
There have been side effects (including blurred vision, dizziness and severe bone, muscle or joint pain) reported with alendronic acid that may affect your ability to drive or operate machinery. Individual responses to alendronic acid may vary (See Section 4 POSSIBLE SIDE EFFECTS).

Important information about some of the ingredients of Alendronic Acid oral solution
This medicinal product contains sunset yellow (E110), methyl- and propyl-parahydroxybenzoates (E218, E216) that may cause allergic reactions (possibly delayed). *Allergy is more common if you are allergic to aspirin. You should check with your doctor or pharmacist if you are not sure.*

This medicinal product contains 0.15 vol % ethanol (alcohol) i.e. up to 115 mg per dose, equivalent to 3 ml beer, 1.3 ml wine per dose. This may be harmful to those suffering from alcoholism and also should be taken into account in high risk groups such as patients with liver disease or epilepsy.

3) How to take Alendronic Acid oral solution

Always take Alendronic Acid oral solution exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The recommended dosage is one 70mg unit-dose (100ml) <u>once weekly.</u>

Follow these instructions carefully to make sure you will benefit from Alendronic Acid oral solution.
Choose the day of the week that best fits your schedule. Every week, take Alendronic Acid oral solution on your chosen day.

It is very important to follow these instructions to help the Alendronic Acid oral solution reach your stomach quickly and help reduce the chance of irritating your gullet (oesophagus - the tube that connects your mouth with your stomach).
- After getting up for the day and before taking any food, drink, or other medicine, swallow your Alendronic Acid oral solution.
- Drink one entire bottle of solution followed by at least 30 ml (one sixth of a glass) of plain water. Additional water (plain) may be taken.
- Do not take with mineral water (still or sparkling), coffee, tea, juice or milk.
- Do not lie down – stay fully upright (sitting, standing or walking) – for at least 30 minutes after taking the solution. <u>Do not lie down until after your first food of the day.</u>
- Do not take Alendronic Acid oral solution at bedtime or before arising for the day
- If you develop difficulty or pain upon swallowing, chest pain or new or worsening heartburn, contact your doctor
- After swallowing your Alendronic Acid oral solution, wait at least 30 minutes before taking your first food, drink, or other medicine of the day, including antacids, calcium supplements and vitamins. Alendronic Acid oral solution is effective only if taken when your stomach is empty.

If you take more Alendronic Acid oral solution than you should
If you take too much solution 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 Alendronic Acid oral solution
If you miss a dose, just take the dose on the morning after you remember. *Do not take two doses on the same day*.
Return to taking one dose once a week, as originally scheduled on your chosen day.

If you stop taking Alendronic Acid oral solution
It is important that you continue taking Alendronic Acid oral solution for as long as your doctor prescribes the medicine. Alendronic Acid oral solution can treat your osteoporosis only if you continue to take the solution.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4) Possible side effects

Like all medicines, Alendronic Acid oral solution 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 and 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 or if you are receiving treatment for cancer.
- 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

Other side effects include:

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

Common: may affect up to 1 in 10 people
- abdominal pain; uncomfortable feeling in the stomach or belching after eating; indigestion, constipation; full or bloated feeling in the stomach; diarrhoea; flatulence
- headache, dizziness
- Joint swelling
- Itching
- Alopecia (Hair Loss)
- Tiredness / weakness,
- swelling in the hands or legs
- Whirling or spinning motion associated with dizziness (vertigo)

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 1,000 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
- 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.

Tell your doctor or pharmacist promptly about these or any other unusual symptoms.

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

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects you can help provide more information on the safety of this medicine.

5) How to store Alendronic Acid oral solution

- **Keep out of the sight and reach of children.**
- Do not use after the expiry date printed on the carton or bottle label after 'EXP'. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- If the medicine becomes discoloured or show any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- 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) Contents of the pack and other information

What Alendronic Acid oral solution contains
The active substance is alendronate sodium trihydrate. Each 100ml of solution contains 70mg alendronic acid as alendronate sodium trihydrate.

The other ingredients are:
xanthan gum (E415), sodium cyclamate (E952), sucralose (E955), sunset yellow FCF (E110), methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), orange flavour containing ethanol and butylated hydroxyanisole, purified water.

What Alendronic Acid oral solution looks like and contents of the pack
Alendronic Acid 70mg oral solution is an opalescent orange coloured solution. It is available in clear bottles with a tamper-evident closure in a pack size of 4 bottles.
Each bottle contains 100 ml of solution and is for single use only.

PL 46420/0030	Alendronic Acid 70mg oral solution Bonasol 70mg Oral Solution	**POM**

Who makes and repackages your medicine?
Your medicine is manufactured by
Pinewood Laboratories Ltd, Ballymacarbry, Clonmel, County Tipperary, Ireland.
Procured from within the EU and repackaged by the Product Licence holder: Suerte Pharma Ltd, 4/5 Northolt Trading Estate, Belvue Road, Northolt, Middlesex, UB5 5QS.

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For any information about this medicine or to request a copy of this leaflet in Braille, large print or audio, please call the PL holder: Suerte Pharma Limited on 020 8839 3000.