

**SCHEDULING STATUS**

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**FOSAGEN 70 mg (tablets)****Alendronic acid****Contains sugar: Lactose monohydrate 158,88 mg****Read all of this leaflet carefully before you start taking FOSAGEN 70 mg**

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

FOSAGEN 70 mg has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

**What is in this leaflet**

1. What FOSAGEN 70 mg is and what it is used for.
2. What you need to know before you take FOSAGEN 70 mg.
3. How to take FOSAGEN 70 mg.
4. Possible side effects.
5. How to store FOSAGEN 70 mg.
6. Contents of the pack and other information.

**1. What FOSAGEN 70 mg is and what it is used for****What is FOSAGEN 70 mg:**

FOSAGEN 70 mg is a tablet containing the active substance alendronic acid (commonly called alendronate) and belongs to a group of non-hormonal medicines called bisphosphonates. FOSAGEN 70 mg prevents the loss of bone that occurs in women after



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they have been through the menopause and helps to rebuild bone. It reduces the risk of spine and hip fractures.

#### **What is FOSAGEN 70 mg used for:**

Your doctor has prescribed FOSAGEN 70 mg to treat your osteoporosis. It reduces the risk of spine and hip fractures.

## **2. What you need to know before you take FOSAGEN 70 mg**

#### **Do not take FOSAGEN 70 mg:**

- if you are hypersensitive (allergic) to alendronic acid or any of the other ingredients of FOSAGEN 70 mg (listed in section 6);
- if you have certain problems with your 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 have severe kidney problems;
- if you are pregnant or breastfeeding.

These tablets should not be given to children.

#### **Warnings and precautions**

#### **Take special care FOSAGEN 70 mg if:**

- you suffer from kidney problems;
- you have, or have recently had, any swallowing or digestive problems;
- you have a disorder of the oesophagus (the tube that connects your mouth to your stomach);
- you are unable to stand or sit upright for at least 30 minutes after taking the tablet;

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- you have been told you have trouble absorbing minerals in your stomach or intestines (malabsorption syndrome);
- 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 are pregnant or breastfeeding.

These tablets should not be given to children.

You may be advised to have a dental check-up before starting treatment with FOSAGEN 70 mg.

It is important to maintain good oral hygiene when being treated with FOSAGEN 70 mg. 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 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

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down less than 30 minutes after taking FOSAGEN 70 mg. These side effects may worsen if patients continue to take FOSAGEN 70 mg after developing these symptoms.

#### **Children and adolescents**

Do not give FOSAGEN 70 mg to children as safety and efficacy have not been established.

#### **Other medicines and FOSAGEN 70 mg**

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines:

Calcium supplements, iron or magnesium, including antacids and mineral supplements and certain laxatives, will interfere with FOSAGEN 70 mg. You must wait at least 30 minutes after taking FOSAGEN 70 mg before taking any other medication.

#### **FOSAGEN 70 mg with food and drink and alcohol**

It is likely that food and beverages (including mineral water) will make FOSAGEN 70 mg less effective if taken at the same time. Therefore, it is important that you follow the advice given in section 3.

#### **Pregnancy and breastfeeding and fertility**

You should not take FOSAGEN 70 mg if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking FOSAGEN 70 mg.

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#### **Driving and using machinery**

It is not always possible to predict to what extent FOSAGEN 70 mg may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which FOSAGEN 70 mg affects them.

There have been side effects (for example blurred vision, dizziness and severe bone, muscle or joint pain) reported with FOSAGEN 70 mg that may affect your ability to drive or operate machinery (see section 4).

#### **FOSAGEN 70 mg contains lactose**

FOSAGEN 70 mg contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Patients with the rare hereditary conditions of lactose intolerance should not take FOSAGEN 70 mg

### **3. How to take FOSAGEN 70 mg**

- Do not share medicines prescribed for you with any other person.
- Always take FOSAGEN 70 mg exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- Your doctor will tell you how long your treatment with FOSAGEN 70 mg will last.
- If you have the impression that the effect of FOSAGEN 70 mg is too strong or too weak, tell your doctor or pharmacist.

#### **The usual dose is:**

Take one FOSAGEN 70 mg tablet once a week.

Follow these instructions carefully.

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- 1) Choose the day of the week that best fits your schedule. Every week, take one FOSAGEN 70 mg tablet on your chosen day.

*It is very important to follow instructions 2), 3), 4) and 5) to help the FOSAGEN 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 FOSAGEN 70 mg tablet whole with a full glass of water only (not mineral water) (not less than 200 ml), so that FOSAGEN 70 mg is adequately absorbed.
  - 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 because of the possibility of mouth ulceration.

- 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 FOSAGEN 70 mg 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 FOSAGEN 70 mg and contact your doctor.
- 6) After swallowing your FOSAGEN 70 mg tablet, wait at least 30 minutes before taking your first food, drink, or other medicine of the day, including antacids, calcium supplements and vitamins. FOSAGEN 70 mg is effective only if taken when your stomach is empty.

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#### **If you take more FOSAGEN 70 mg than you should**

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

#### **If you forget to take a dose of FOSAGEN 70 mg**

Do not take a double dose to make up for forgotten individual doses.

#### **If you stop taking FOSAGEN 70 mg**

It is important that you take FOSAGEN 70 mg for as long as your doctor prescribes the medicine.

## **4. Possible side effects**

FOSAGEN 70 mg can have side effects.

Not all side effects reported for FOSAGEN 70 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking FOSAGEN 70 mg, please consult your healthcare provider for advice.

**If any of the following happens, stop taking FOSAGEN 70 mg and tell your doctor immediately or go to the casualty department at your nearest hospital:**

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to FOSAGEN 70 mg. You may need urgent medical attention or hospitalisation.

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**Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:**

- heartburn; difficulty swallowing; pain upon swallowing; ulceration of the oesophagus (the tube that connects your mouth with your stomach), which can cause chest pain, heartburn or difficulty or pain upon swallowing,
- 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,
- ear pain, discharge from the ear, and/or an ear infection. These could be signs of bone damage in the ear,
- transient flu-like symptoms, such as aching muscles, generally feeling unwell and sometimes with fever usually at the start of treatment.

These are all serious side effects. You may need urgent medical attention.

**Tell your doctor if you notice any of the following:**

The following side effects have been reported frequently:

- joint swelling,
- abdominal pain; uncomfortable feeling in the stomach or belching after eating; constipation; full or bloated feeling in the stomach; diarrhoea; flatulence,



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- hair loss,
- headache,
- dizziness,
- tiredness,
- swelling in the hands or legs.

The following side effects have been reported less frequently:

- nausea; vomiting,
- black or tar-like stools,
- blurred vision; pain or redness in the eye,
- rash; redness of the skin,
- taste disturbance,
- 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),
- rash made worse by sunlight,
- mouth ulcers.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

#### **Reporting of side effects**

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the “**6.04 Adverse Drug Reactions Reporting Form**”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>

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By reporting side effects, you can help provide more information on the safety of FOSAGEN 70 mg.

## 5. How to store FOSAGEN 70 mg

Store at or below 25 °C.

Keep the container in the outer carton.

Protect from light.

Do not store in a bathroom.

Do not use after the expiry date stated on the label/carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## 6. Contents of the pack and other information

### What FOSAGEN 70 mg contains:

The active substance is alendronic acid.

The other ingredients are:

Lactose monohydrate

Microcrystalline cellulose (pH 102)

Povidone (K29 - 32)

Croscarmellose sodium

Magnesium stearate

### What FOSAGEN 70 mg looks like and contents of the pack:

#### What FOSAGEN 70 mg looks like:

White normal bi-convex tablets 9,5 mm in diameter, embossed "AD70" on one side and "G" on the reverse.

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**Contents of the pack:**

4, 8 or 12 tablets in green PVC and aluminium foil blister strips packaged into an outer cardboard carton.

4, 8 or 12 tablets in white securitainers with white polyethylene caps and optional polyethylene ullage filler.

**Holder of Certificate of Registration and Manufacturer**

VIATRIS HEALTHCARE (Pty) Ltd.

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1600

Republic of South Africa

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**Access to the corresponding Professional Information**

Can be obtained on the SAHPRA website.