PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PROPRIETARY NAME STRENGTH AND PHARMACEUTICAL-FORM

ALENDRONATE 70 OETHMAAN tablets

Read all of this leaflet carefully before you start taking ALENDRONATE 70 OETHMAAN.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **ALENDRONATE 70 OETHMAAN** 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.

1. WHAT ALENDRONATE 70 OETHMAAN CONTAINS

ALENDRONATE 70 OETHMAAN tablets contains 70 mg alendronate sodium as the active ingredient.

ALENDRONATE 70 OETHMAAN tablets also contains the following inactive ingredients: Colloidal anhydrous silica, croscarmellose sodium, magnesium stearate and microcrystalline cellulose.

Sugar Free.

2. WHAT ALENDRONATE 70 OETHMAAN IS USED FOR

ALENDRONATE 70 OETHMAAN tablets belong to a class of medicines called bisphosphonates.

ALENDRONATE 70 OETHMAAN is used to treat a disease called osteoporosis. **ALENDRONATE 70 OETHMAAN** will decrease bone loss and reduce your risk of developing fractures (bones from breaking).

3. BEFORE YOU TAKE ALENDRONATE 70 OETHMAAN:

Do not take **ALENDRONATE 70 OETHMAAN** if:

- You are hypersensitive (allergic) to alendronate sodium or any of the other ingredients. (see "**WHAT ALENDRONATE 70 OETHMAAN CONTAINS"**).

- You are unable to stand or sit upright for at least 30 minutes after taking the tablets.

- You have certain disorders of the oesophagus (the tube through which you swallow and which connects your mouth with your stomach).

- Your doctor has told you that you currently have low blood calcium.

- You are pregnant or breastfeeding.

- You are below 18 years of age.

If you answer yes to any of the following questions please consult with your doctor before starting your treatment:

Any medical problems you have or have had, including known kidney disease, and about any allergies. If you have severe bone, joint or muscle pain, or if you have or have previously had fracture of the thigh bone while on long-term treatment with **ALENDRONATE 70 OETHMAAN**.

If you have any swallowing, stomach or digestive problems.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your health care provider for advice before taking **ALENDRONATE 70 OETHMAAN**.DO NOT TAKE **ALENDRONATE 70 OETHMAAN** until you have talked to your doctor. Consult your doctor immediately if you become pregnant while taking this medicine.

Use in children

ALENDRONATE 70 OETHMAAN cannot be used in children and should not be given to them.

Taking other medicines with ALENDRONATE 70 OETHMAAN

See **"How to take ALENDRONATE 70 OETHMAAN"**

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

If you are taking other medicines on a regular basis including complimentary or traditional medicines, use of **ALENDRONATE 70 OETHMAAN** with those other medicines may cause undesirable interactions. Other oral medicines, such as calcium supplements and antacids and asprin-like, may interfere with the absorption of **ALENDRONATE 70 OETHMAAN**. Please consult your doctor or pharmacist.

4. HOW TO TAKE ALENDRONATE 70 OETHMAAN

Do not share medicines prescribed for you with any other person.

You must remember the following important things when you take your **ALENDRONATE 70 OETHMAAN** tablets to make sure you will benefit the most.

1. After you get up in the day, swallow your **ALENDRONATE 70 OETHMAAN** tablet with a full glass of plain water only. Do not suck or chew the tablet. Do not take with any other liquid like mineral water coffee or tea, fruit juice or any other soft drink.

2. After swallowing your **ALENDRONATE 70 OETHMAAN** tablet do not lie down – stay fully upright (sitting or standing) for at least 30 minutes and do not eat your first food of the day also for at least 30 minutes.

3. Do not take **ALENDRONATE 70 OETHMAAN** at bedtime or before getting up for the day.

If you do all the above things, the **ALENDRONATE 70 OETHMAAN** tablet will reach your stomach quickly and the potential for irritation of your oesophagus (the tube through which you swallow and that connects your mouth with your stomach).

4. After swallowing your **ALENDRONATE 70 OETHMAAN** tablet, wait at least 30 minutes before taking your first food, beverage, or other medication of the day, including antacids, calcium supplements and vitamins.

ALENDRONATE 70 OETHMAAN is effective only if taken when your stomach is empty.

5. If you develop difficulty or pain when you swallow, chest pain, or new or worsening heartburn, stop taking **ALENDRONATE 70 OETHMAAN** and call your doctor.

6. Take one **ALENDRONATE 70 OETHMAAN** tablet once a week as prescribed by your doctor.

7. It is important that you continue taking **ALENDRONATE 70 OETHMAAN** for as long as your doctor prescribes it. **ALENDRONATE 70 OETHMAAN** can treat your osteoporosis or help reduce the risk of developing osteoporosis induced bone fracture, only if you continue to take it.

You should always tell your doctor about all other medicines you are taking, including those obtained without a prescription.

If you take more ALENDRONATE 70 OETHMAAN than you should

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

If you take too much tablets, drink a full glass of milk and contact your doctor immediately. Do not try to vomit. Do not lie down.

If you forget to take a dose of ALENDRONATE 70 OETHMAAN

Do not take a double dose of **ALENDRONATE 70 OETHMAAN** to make up for the forgotten individual doses.

Take **ALENDRONATE 70 OETHMAAN** once weekly as prescribed. However, if you miss a dose in the morning it should not be taken later during the day, but should rather be taken the next morning according to the weekly schedule. Do not take two tablets at the same time.

5. POSSIBLE SIDE-EFFECTS

ALENDRONATE 70 OETHMAAN may have unintended or undesirable effects.

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

Frequent side effects: Digestive disturbances such as nausea, vomiting, or black and/or bloody stools. Some digestive disturbances may be severe including irritation or ulceration of the oesophagus (the tube that connects your mouth with your stomach), which can cause chest pain, heartburn or difficulty or pain when swallowing.

These reactions may occur especially if patients do not drink a full glass of water with **ALENDRONATE 70 OETHMAAN** and/or if they lie down in less than 30 minutes and before their first food of the day. Oesophageal reactions may worsen if patients continue to take **ALENDRONATE 70 OETHMAAN** after developing symptoms suggesting irritation of the oesophagus.

Less frequently: stomach or other peptic ulcers (some severe) have occurred.

Frequently: Some patients may experience bone, muscle or joint pain or, less frequently, a rash (occasionally made worse by sunlight), hair loss, changed sense of taste, nausea and fracture of the thigh bone in patients on long-term treatment with **ALENDRONATE 70 OETHMAAN**.

- Allergic reactions such as hives, or less frequently, swelling of the face, lips, tongue and/or throat which may cause difficulty in breathing or swallowing may occur.

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

6. STORING AND DISPOSING OF ALENDRONATE 70 OETHMAAN

Store in the original packs at or below 25 °C in the original package.

STORE ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.

Do not use **ALENDRONATE 70 OETHMAAN** after the expiry/use before date 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).

7. PRESENTATION OF ALENDRONATE 70 OETHMAAN

4 tablets packed in aluminium foil blister packed in an outer cardboard carton.

8. IDENTIFICATION OF ALENDRONATE 70 OETHMAAN

A white, round, biconvex film coated tablet debossed with “ALN 70” on one side.

9. REGISTRATION NUMBER

A 40/3.2/0514

10. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Oethmaan Biosims (Pty) Ltd.

207A Sherwood House

Greenacres Office Park

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2195

11. DATE OF PUBLICATION

Date of registration: 01 December 2006

Date of last approval by Council: 19 April 2013