

# DENSATE 70

*Alendronate (as alendronate sodium)*

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## Consumer Medicine Information

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### What is in this leaflet

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This leaflet answers some common questions about DENSATE. It is particularly important that you read the sections "When to take it" and "How to take it" before you take this medicine. This leaflet does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking DENSATE against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.** You may need to read it again.

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### What DENSATE is used for

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DENSATE is used to treat osteoporosis.

This condition is caused by changes in the way bone is normally maintained.

### *Understanding bone*

Bone is living, growing tissue. Throughout life, our bodies are breaking down old bone and rebuilding new bone in a continuous cycle. Until our late 20s, while bones are still developing, we gain bone by building more than we lose. From then until about age 35 the process is usually in balance, so that the amount of bone lost is about equal to the amount that is replaced. After about age 35 this balance is disturbed, with bone loss occurring at a slightly faster rate than it can be replaced. In women, after menopause, hormonal changes cause bone loss at an even faster rate. When bone loss is excessive, bones can become thinner and weaker, and therefore are more likely to break.

### *Osteoporosis*

"Osteo" means bone, and "porosis" means something that has holes in it, like a sponge. Therefore, osteoporosis is a disease which causes bones to become more porous, gradually making them weaker, more brittle and likely to break.

Osteoporosis is common in postmenopausal women. The menopause occurs when the ovaries virtually stop producing the female hormone, oestrogen, or are removed (which may occur, for example, at the time of a hysterectomy). At this time, bone is removed faster than it is formed, so bone loss occurs and bones become weaker. The earlier a woman reaches the menopause, the greater the risk of osteoporosis.

Osteoporosis also occurs in men but is less common than in women.

Early on, osteoporosis usually has no symptoms. However, if left untreated it can result in broken bones, also called fractures. Although fractures usually cause pain, fractures of the bones of the spine may go unnoticed until they cause height loss. Fractures may occur during normal, everyday activity, such as lifting, or from minor injury that would not ordinarily fracture normal bone. Fractures usually occur at the hip, spine, or wrist and can lead not only to pain, but also to considerable deformity and disability, such as stooped posture from curvature of the spine, and loss of mobility.

### *How does DENSATE work?*

DENSATE works by slowing down the process of old bone being removed, which allows the bone-forming cells time to rebuild normal bone. DENSATE not only helps prevent the loss of bone but actually helps to rebuild bone and makes bone less likely to fracture. Thus, DENSATE reverses the progression of osteoporosis. DENSATE starts working on the bone cells immediately, but measurable effects on bone mass may not be seen for several months or more.

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

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## Before you take DENSATE

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You should know that in some people, DENSATE can irritate or burn the food pipe (also called oesophagus). The chances of this happening should be reduced when you follow the instructions for 'How to take DENSATE' section in this leaflet.

### *When you must not take it*

#### **Do not take DENSATE if:**

- you have an allergy to DENSATE or any of the ingredients listed at the end of this leaflet
- you have certain disorders of the food pipe (oesophagus) including those that cause difficulty in swallowing
- you are unable to stand or sit upright for at least 30 minutes
- your doctor has told you that you currently have low blood calcium
- your dentist advises you to consult your doctor first

#### **Do not take DENSATE if you are pregnant or breast-feeding.**

DENSATE has not been studied in pregnant or breastfeeding women.

#### **Do not take DENSATE if:**

- the packaging is torn or shows signs of tampering
- the expiry date on the pack has passed.  
If you take this medicine after the expiry date has passed, it may not work.

**If you are not sure whether you should start taking DENSATE, talk to your doctor.**

#### **Do not give DENSATE to a child.**

DENSATE has not been studied in children.

### *Before you start to take it*

#### **Tell your doctor if:**

- you plan to become pregnant or breast-feed
- you have any medical conditions, especially the following:
  - kidney disease
  - swallowing or digestive problems, such as ulcers
- you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.
- you have dental or jaw-bone problems or are planning to have a course of dental surgery.
- you currently smoke or have been a smoker in the past.

**If you have not told your doctor about any of the above, tell them before you take any DENSATE.**

### *Taking other medicines*

**Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.**

Some medicines may affect the way other medicines work.

**Some medicines are likely to interfere with the absorption of DENSATE if taken at the same time. These include:**

- antacids, medicines used to treat indigestion eg Gaviscon, Mylanta
- calcium supplements
- vitamins

**Therefore, take DENSATE at least 30 minutes before taking any of these or other medicines to make sure there is no problem with absorption. Check with your doctor or pharmacist if you are not sure whether you are taking any of these medicines.**

You can take aspirin while you are being treated with DENSATE. However, both aspirin and DENSATE may increase the chance of stomach upsets.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking DENSATE.

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## How to take DENSATE

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### *How much to take*

**Take DENSATE only when prescribed by your doctor.**

The usual dose of DENSATE is 70 mg tablet once a week.

**Choose the day of the week that best fits your schedule. Every week, take one tablet of DENSATE on your chosen day.**

**Follow all directions given to you by your doctor carefully.**

They may differ from the information contained in this leaflet.

**If you do not understand the instructions on the box, ask your doctor or pharmacist for help.**

### *When and how to take it*

**Take DENSATE after getting up for the day. Do not take it at bedtime.**

**Swallow one tablet whole with a full glass of plain water.**

Do not take any food, medicines or drinks other than plain tap water with your DENSATE. It is important to take DENSATE with plain water only, not mineral water. Food, other drugs, mineral water and other drinks, including fruit juices, coffee and tea, will reduce the effect of DENSATE by interfering with the absorption into the body.

**Stay upright for at least 30 minutes after swallowing DENSATE and do not take any food, medicines or drinks other than plain tap water during this time.**

**Do not lie down immediately after swallowing it.** It is important to stay upright (sitting, standing or walking around) for at least 30 minutes after swallowing your tablet. **It is also very important to stay upright until after you have eaten your first food of the day.** These actions will help make sure your dose of DENSATE reaches your stomach quickly and help reduce the potential for irritation to your food pipe (oesophagus).

DENSATE is effective only if taken when your stomach is empty. Food, drinks other than plain water, and other medicines will lessen the effect of DENSATE by interfering with its absorption into the body.

**Do not chew or suck on a tablet of DENSATE.**

Mouth ulcers may occur if the tablet is chewed or dissolved in the mouth.

### *How long to take it*

It is important that you continue taking DENSATE for as long as your doctor prescribes. DENSATE can only treat your osteoporosis, by helping prevent further loss of bone and continuing to rebuild bone, if you take it every week.

### *If you forget to take it*

**If you miss a tablet, 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 are not sure about what to do, talk to your doctor or pharmacist.**

**If you have trouble remembering to take your DENSATE, ask your pharmacist for some hints.**

### *If you take too much (overdose)*

**Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much DENSATE. Do this even if there are no signs of discomfort or poisoning.**

**If you take too many tablets at one time, drink a full glass of milk. Do not induce vomiting. Do not lie down.**

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## While you are taking DENSATE

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### *Things you must do*

**If you develop difficulty or pain upon swallowing, chest pain, or new or worsening heartburn, stop taking DENSATE and call your doctor.**

**If you become pregnant while taking DENSATE, stop taking DENSATE and tell your doctor.**

**If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking DENSATE.**

**If you develop a toothache or require a dental procedure, tell your dentist that you are taking DENSATE.**

**If you develop new or unusual pain in your hip or thigh, tell your doctor.**

Rarely, patients have experienced fracture in a specific part of the thigh Bone.

**Make sure you have an adequate intake of calcium in your diet.**

Your doctor, dietician or pharmacist can tell you what foods you should eat.

### *Things you must not do*

**Do not give DENSATE to anyone else, even if they have the same condition as you.**

### *Things to be careful of*

**There have been side effects reported with DENSATE that may affect your ability to drive or operate machinery. Individual responses to DENSATE may vary. (See Side Effects).**

### *Things that would be helpful for your osteoporosis*

Some self help measures suggested below may help your osteoporosis. Talk to your doctor or pharmacist about these measures and for more information.

- **Exercise** - can be helpful in building and maintaining strong bones. Regular exercise such as a brisk walk is a good idea. Talk to your doctor before you begin any exercise program.
- **Diet** - eat a balanced diet. You may need to increase the amount of calcium in your diet by eating calcium-rich foods or taking a calcium supplement. Your doctor will advise you.
- **Smoking** - appears to increase the rate at which you lose bone and, therefore, may increase your risk of fracture. Your doctor may ask you to stop smoking or at least cut down.
- **Alcohol** - your doctor may advise you to cut down the amount of alcohol you drink. If you drink excessively on a regular basis, you may increase your risk of developing osteoporosis.

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## Side Effects

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking DENSATE.**

DENSATE helps most people with osteoporosis, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

**Ask your doctor or pharmacist to answer any questions you may have.**

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

- stomach pain, gas in the stomach or bowel, wind
- an uncomfortable feeling in the stomach or belching after eating, also called dyspepsia, or heartburn
- feeling sick (nausea), vomiting
- constipation, diarrhoea
- headache
- aching muscles, joints and/or bones, which rarely can be severe.
- flu-like symptoms typically at the start of treatment, such as aching muscles, generally feeling unwell and rarely fever.
- swelling of joints
- dizziness or spinning sensation
- unusual tiredness or weakness
- swelling of hands, ankles or feet
- hair loss
- changed sense of taste

Most of these are the more common side effects of DENSATE. For the most part, these have been mild.

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

- skin rash or redness of the skin, sometimes made worse by sunlight, itchiness
- mouth ulcers
- blurred vision, pain or redness in the eye

- symptoms of low blood calcium levels including muscle cramps or spasms or tingling sensation in the fingers or around the mouth
- new or unusual pain in your hip or thigh

These side effects are rare, and very rarely, may be serious.

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

- Jaw-bone or dental problems (including toothache). Jaw-bone problems may include infection, and delayed healing after a tooth extraction or other work that involves drilling into the jawbone.

These side effects are rare and may be serious.

**If any of the following happen, stop taking DENSATE and tell your doctor immediately:**

- difficulty or pain upon swallowing
- chest pain
- new or worsening heartburn

These side effects may be due to irritation or ulceration of the food pipe. They may worsen if you continue taking DENSATE. Rarely, these side effects may be serious.

**If any of the following happen, stop taking DENSATE and tell your doctor immediately or go to accident and emergency at your nearest hospital:**

- swelling of the face, lips, mouth, throat or tongue which may cause difficulty in breathing or swallowing
- pinkish, itchy swellings on the skin, also called hives or nettle rash
- severe skin reactions
- black tar-like and/or bloody stools

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

If you have the swelling described above, you may be having a serious allergic reaction to DENSATE.

Rarely, stomach or duodenal ulcers (some severe) have occurred, but it is not known whether these were caused by DENSATE.

**Other side effects not listed above may also occur in some patients.**

**Tell your doctor if you notice any other effects.**

Do not be alarmed by this list of possible side effects. You may not experience any of them.

DENSATE is not addictive.

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## After taking DENSATE

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### *Storage*

**Keep your tablets in the blister pack until it is time to take them.**

If you take the tablets out of the blister pack they may not keep well.

**Keep DENSATE in a cool dry place where the temperature stays below 25°C. Do not freeze the product. Do not store it or any other medicine in the bathroom or near a sink.**

**Do not leave it in the car or on window sills.**

Heat and dampness can destroy some medicines.

**Keep it where children cannot reach it.**

A locked cupboard at least one-and-a-half meters above the ground is a good place to store medicines.

### *Disposal*

**If your doctor tells you to stop taking DENSATE, or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.**

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## Product Description

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### *What it looks like*

DENSATE comes in pack size of 4 tablets in blister.

DENSATE 70 (AUST R 171794)

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

### *Ingredients*

#### **Active Ingredient:**

Alendronate (as alendronate sodium)

Each tablet contains 70mg of Alendronate as alendronate sodium.

#### **Other Ingredients:**

- Cellulose - microcrystalline (Avicel PH-101 & PH-102)
- Starch-maize
- Sodium starch glycollate type A
- Povidone
- Magnesium stearate.

Please read this leaflet carefully before you start taking DENSATE. You may wish to keep it to read again.

### *Name and Address of the Sponsor*

#### **Aurobindo Pharma Australia Pty Ltd**

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#### **Date of Approval**

13 May 2011