



National Prescribing Service Limited

31 August 2007



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Dr Sam Sample  
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Prescribing  
Practice Review

**No. 39**  
**Preventing**  
**osteoporosis**  
**and reducing**  
**fracture risk**

Dear Dr Sample,

The enclosed *Prescribing Practice Review* summarises important issues in the prevention and management of osteoporosis, especially in postmenopausal women.

***Advise on adequate physical activity, calcium and vitamin D, especially in the young and elderly***

Intervene early to maximise peak bone mass, especially during childhood and adolescence through advice on physical activity levels, exposure to sunlight and adequate calcium and vitamin D.

***Use specific anti-osteoporotic drugs after osteoporotic fracture in postmenopausal women***

The goal of drug therapy in osteoporosis is to prevent fragility fractures in those at high risk. Bisphosphonates are first-line therapies for the management of osteoporosis.

***Ensure sufficient vitamin D and calcium in prevention and treatment of osteoporosis***

Adequate vitamin D and calcium is required to maximise the benefits of anti-osteoporotic drugs.

***Optimise patient compliance with bisphosphonates to achieve fracture risk reduction***

Check compliance regularly and motivate patients to persist with treatment. The *PPR* provides possible approaches to improve compliance with long-term drug therapies.

***Use bisphosphonates carefully to avoid adverse effects***

Provide patients with clear instructions, both verbal and written, about how to use bisphosphonates to avoid adverse gastrointestinal effects, and maximise bioavailability. Bisphosphonate-induced osteonecrosis of the jaw is rare — the *PPR* identifies some strategies to minimise risk.

Your confidential prescribing data are also enclosed for your information.

The Clinical Audit: *Osteoporosis prevention and treatment* is now available. See the enclosed enrolment form for more information.

Yours sincerely,

Dr Roger Boyd  
Chair, National Prescribing Service Limited

NPS is an independent, non-profit organisation for Quality Use of Medicines,  
funded by the Australian Government Department of Health and Ageing.

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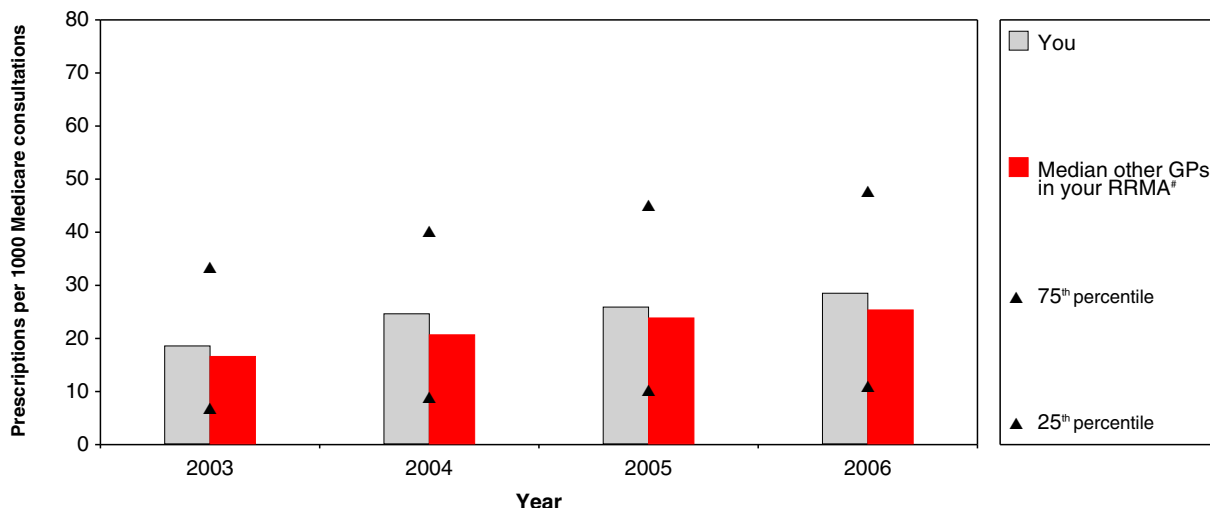
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## Your confidential prescribing data

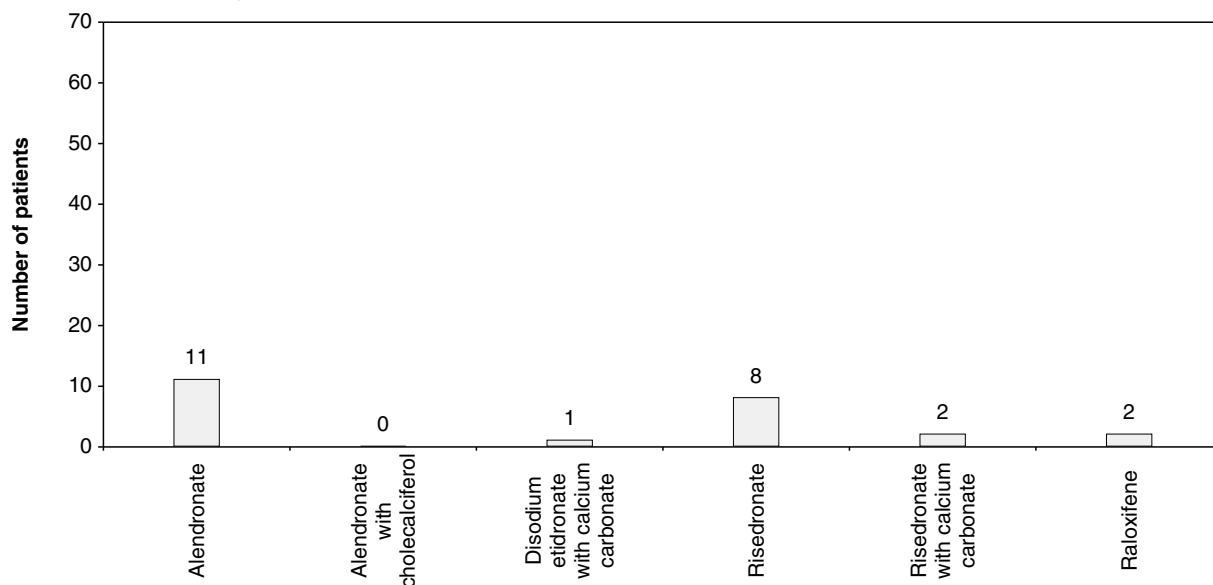
The data presented from Medicare Australia include all prescriptions dispensed for oral bisphosphonates and raloxifene meeting the PBS criteria for the treatment of osteoporosis. As all the items are above the general patient co-payment, data capture is complete. Alendronate 10mg was removed from the PBS in May 2004. The combination products of risedronate with calcium carbonate and alendronate with cholecalciferol became PBS listed in April and August 2006 respectively.



### Bisphosphonate and raloxifene use



### Your prescribing of individual bisphosphonates and raloxifene - 2006



In 2006, 100% of your patients were using bisphosphonates as weekly therapy. Nationally, 99% of patients were using bisphosphonates as weekly therapy.

### Practice points

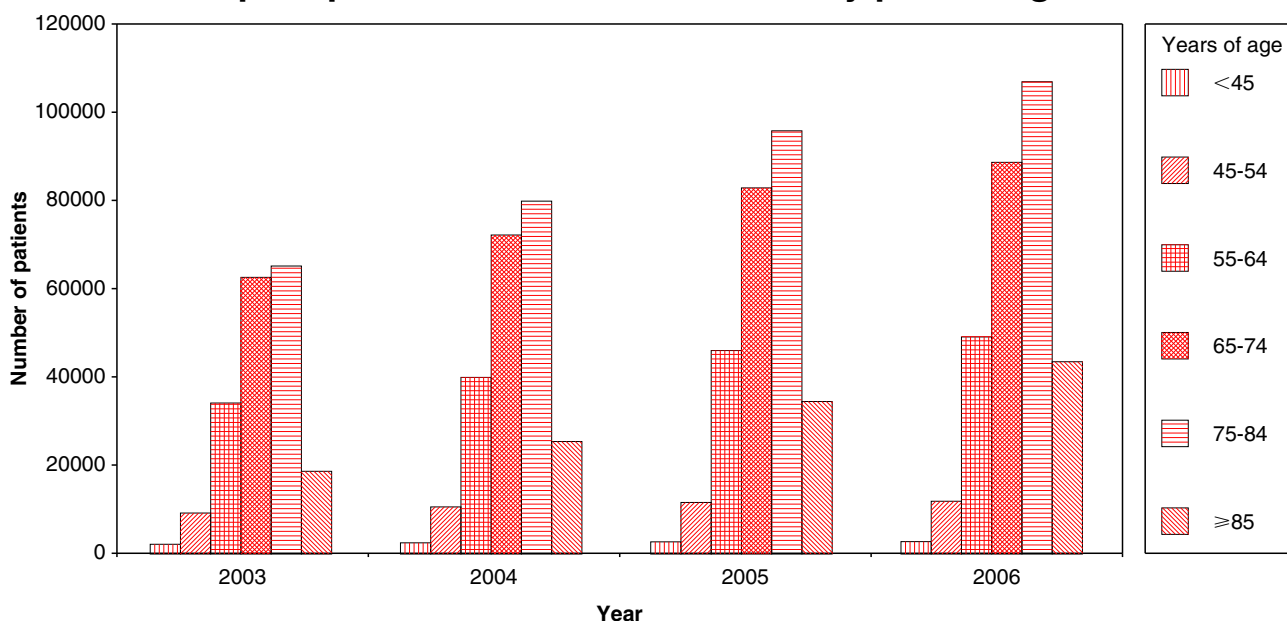
- Alendronate and risedronate are recommended as first-line therapy for osteoporosis in men and postmenopausal women as they reduce vertebral and non-vertebral (including hip) fracture rates.
- Raloxifene reduces the risk of vertebral, but not non-vertebral fractures in postmenopausal women with osteoporosis. Raloxifene is an alternative treatment for postmenopausal women with osteoporosis who are intolerant to bisphosphonates and / or at high risk of breast cancer.
- Etidronate only prevents vertebral fractures in patients who have established osteoporosis and this is reflected by its low use.
- For patients with osteoporosis using anti-osteoporotic therapy, check if they are receiving adequate calcium or vitamin D. Note that combination products (risedronate with calcium carbonate and alendronate with cholecalciferol) may not contain sufficient vitamin D or calcium.

### Your prescribing of bisphosphonates by patient age and sex - 2006

	Number of patients					
	<45 years	45-54 years	55-64 years	65-74 years	75-84 years	≥85 years
Male	0	0	0	3	1	0
Female	0	1	1	5	9	2

In 2006, 18% of your patients using bisphosphonates were male. Nationally, 16% of patients using bisphosphonates were male.

### National bisphosphonate and raloxifene use by patient age

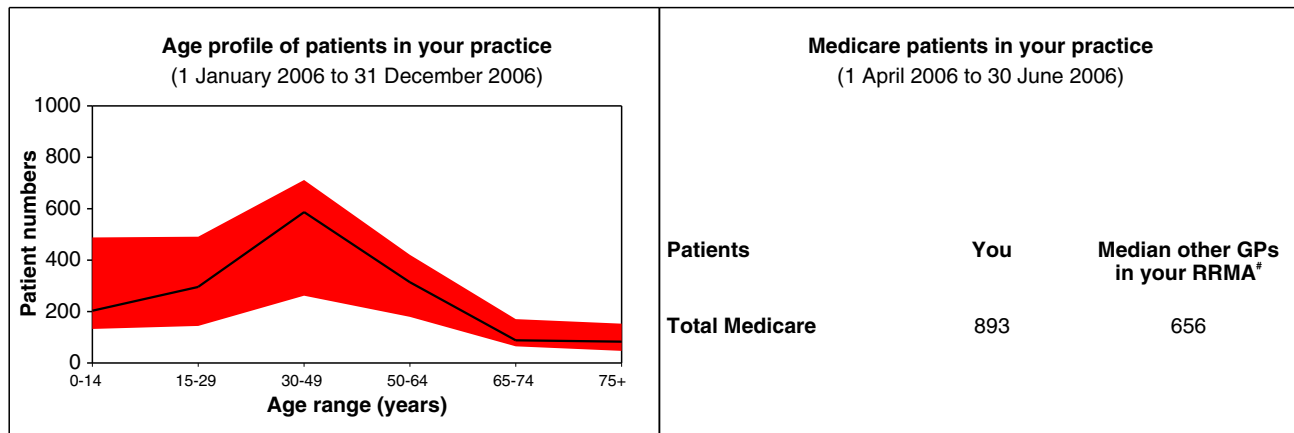


### Practice points

- Is your prescribing of bisphosphonates in both male and female populations adequate?
- Three percent of Australians reported having osteoporosis in the 2004-05 National Health Survey. This may be a significant underestimate, as self-reports are likely to be limited to post-fracture diagnosis.<sup>1</sup>
- Osteoporotic fractures occur in 1 in 2 women and 1 in 3 men over the age of 60 years, in Australia.<sup>2,3</sup>
- Although osteoporotic fractures are less common in men than in women, when they occur, these fractures are associated with higher disability and death than in women.<sup>4</sup>
- The greatest increase in bisphosphonate and raloxifene use, in the above graph, was in the age group 75-84 years: 7% of this age group was receiving therapy in 2003 vs. 11% in 2006.

## Practice profile

Some data shown earlier are presented as prescribing rates (per 1000 Medicare consultations) to adjust for volume of service. Age profile of patients in your practice is provided to assist you to interpret your prescribing data.



The black line represents the age profile of patients in your practice. 25% to 75% of other GPs in your RRMA<sup>#</sup> fall within the shaded area.

Data from a three month period (1 April 2006 to 30 June 2006) that best represent your patient mix have been provided.

## Notes

@ Data shown are an aggregate for all your provider locations.

# The comparator group "other GPs in your RRMA" includes all prescribers currently located in a similar geographical region i.e. 1. capital cities, 2. other metropolitan centres, 3. large rural centres, 4. small rural centres, 5. other rural centres, 6. remote centres and 7. other remote centres.

Your RRMA peer group is 1.

▲ 25% to 75% of "other GPs in your RRMA" fall in the range shown by the triangular symbols.

## Confidentiality

NPS has a contract with Medicare Australia to provide your prescribing feedback data directly to you. NPS does not have access to these data. The data contained in this feedback are not used for any regulatory purposes.

Discrepancies may occur between the data provided and your own prescribing practice. This may be due to either inaccurate recording of your prescriber number in the pharmacy or your prescription pad having been used by another doctor.

If you consider your individual data to be incorrect, have other data queries or general feedback please contact NPS on 02 8217 8700 or by email at [info@nps.org.au](mailto:info@nps.org.au)

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## Preventing osteoporosis and reducing fracture risk

### Key Messages

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- Advise on adequate physical activity, calcium and vitamin D, especially in the young and elderly
  - Use specific anti-osteoporotic drugs after osteoporotic fracture in postmenopausal women
  - Ensure sufficient vitamin D and calcium in prevention and treatment of osteoporosis
  - Optimise patient compliance with bisphosphonates to achieve fracture risk reduction
  - Use bisphosphonates carefully to avoid adverse effects
- 

Osteoporosis is a major public health problem in Australia. Osteoporotic fractures occur in 1 in 2 women and 1 in 3 men over the age of 60 years, causing morbidity and premature mortality.<sup>1,2</sup> The annual health care costs in Australia are estimated at over \$7 billion.<sup>3</sup> Lifestyle interventions and drug therapy can help to reduce the impact of osteoporotic fractures. This *Prescribing Practice Review* deals with the prevention and treatment of osteoporosis in postmenopausal women.

### Advise on adequate physical activity, calcium and vitamin D, especially in the young and elderly

**Provide advice on lifestyle interventions early in life**

Modifying lifestyle-related risk factors can help reduce the risk of osteoporosis later in life.<sup>4,5</sup> Advise families about diet and physical activity to maximise peak bone mass in adolescence.

**Encourage weight-bearing exercise, especially in children and adolescents**

Regular weight-bearing exercise in childhood and early puberty builds bone mass and strength more effectively than exercise in adulthood.<sup>4,6</sup> For healthy children (> 8 years of age) and adolescents, recommend regular physical activity (at least 10 and up to 60 minutes on most days of the week) that includes weight-bearing and jumping activities.<sup>5</sup>

In healthy adults, (including postmenopausal women), weight bearing exercise and moderate to high-impact resistance training can help increase bone mass or slow the rate of bone loss due to ageing.<sup>2,6</sup>

In people with osteoporosis the goal of exercise is to prevent falls. Recommend low-impact exercise that improves muscle strength and balance (e.g. Tai Chi)<sup>3</sup>, and avoid vigorous exercise, as this may cause fractures. There is no evidence that weight-bearing exercise reduces the risk of osteoporotic fracture.

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**Promote adequate dietary calcium in infants, children and adolescents**

Average calcium intake in Australia is well below recommended levels (especially in young women)<sup>4,7</sup>

Adequate calcium is critical during childhood and adolescence, when bone mass accrual is greatest.<sup>4,5</sup>

Encourage families to consume calcium-rich, low-fat (for children over 2 years of age) dairy and non-dairy foods as part of a well-balanced diet.<sup>4,5</sup>

**Recommend sources of calcium and the daily intake needed for all age groups**  
(see *NPS News 53*)

The recommended daily intake of calcium for children and adolescents is:

- Children (5–9 years): 800–1000 mg daily
- Children and adolescents (9–18 years): 1000–1300 mg daily.<sup>4,5</sup>

Adequate calcium intake can be provided by 3 serves of dairy food per day (4 for adolescents) — 1 serve = 250 mL milk or 200 g yoghurt or 40 g cheddar cheese.<sup>4,5</sup>

Calcium-rich non-dairy foods (e.g. almonds, beans, dried figs, tofu, broccoli, bok choy, tinned salmon and sardines) and calcium-fortified foods are a good option for people who cannot tolerate dairy products. They may also be recommended for people unable to consume the adequate number of serves of dairy food per day.

Calcium supplements are necessary when dietary intake is insufficient, which is common in older people.<sup>2</sup>

**Advise on the amount of sunlight exposure to prevent vitamin D deficiency**

Vitamin D is essential for calcium absorption. Exposing the hands, face and arms to direct sunlight (without sunscreens or glass barrier) for 5–15 minutes 4–6 times a week can prevent vitamin D deficiency.<sup>8</sup> Recommended exposure times will vary depending on skin type, latitude and season (see *NPS News 53*). Elderly people and people with dark skin need more frequent exposure.<sup>9</sup>

Prolonged sun exposure has no added benefit for vitamin D synthesis and increases the risk of skin cancer.<sup>9–11</sup>

## Use specific anti-osteoporotic drugs after osteoporotic fracture in postmenopausal women

**Alendronate and risedronate are first line for established osteoporosis in postmenopausal women**

Alendronate reduces the relative risk of vertebral and non-vertebral (including hip) fractures by about 50% in postmenopausal women with established osteoporosis. Risedronate also reduces the relative risk of vertebral fractures by about 50%, and the risk of non-vertebral and hip fractures by 20% to 40%.<sup>12–16</sup> As such these bisphosphonates are considered first-line osteoporotic treatment, especially for elderly women who are at high risk of hip fracture. In the Fracture Intervention Trial, alendronate reduced the absolute risk of a radiographically detected\* vertebral fracture (8% vs 15% with placebo, NNT = 14) and any clinically diagnosed† fracture (13.6% vs 18.2% with placebo, NNT = 22) over 3 years in postmenopausal women with existing vertebral fractures.<sup>17</sup>

In a similar population, risedronate reduced the absolute risk of a new radiographically detected vertebral fracture over 3 years<sup>§</sup> (11.3% vs 16.3% with placebo, NNT = 20) and non-vertebral fractures (5.2% vs 8.4% with placebo, NNT = 31).<sup>18</sup>

\* Defined as a decrease of 20% and at least 4 mm in any vertebral height from the baseline radiograph to the end of the study.

† Vertebral or non-vertebral fractures at any site that came to medical attention, and were confirmed by radiograph or bone scan.

§ Defined as a 15% reduction or more in the anterior, posterior or middle vertebral height and a change from grade 0 (normal) to grades 1 (mild), 2 (moderate) or 3 (severe).

**Reserve other bisphosphonates for second-line use**

Ibandronic acid and etidronate reduce the risk of vertebral fractures. Unlike alendronate and risedronate, there is no evidence that they reduce the risk of non-vertebral fractures, and therefore they may be less suitable for women at high risk of hip fracture.

Daily ibandronic acid has been shown to reduce the relative risk of a radiographically detected vertebral fracture by about 62% in postmenopausal women with established osteoporosis (absolute risk 4.7% vs 9.6% with placebo).<sup>19</sup> There is less evidence for the efficacy and safety of ibandronic acid in fracture prevention compared with other bisphosphonates. Evidence for the efficacy and tolerability of once-monthly ibandronic acid in vertebral fracture risk reduction has been largely extrapolated from studies of daily dosing.<sup>20</sup>

Reserve ibandronic acid as an alternative option for postmenopausal women who cannot tolerate other bisphosphonates or a more frequent dosing regimen.<sup>21</sup>

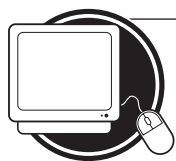
Etidronate reduces the relative risk of vertebral fractures by between 40% and 50%.<sup>12-14</sup> It may be used if alendronate or risedronate are not tolerated, but has a more complex cyclical dose regimen that may be less convenient for some people.<sup>21</sup>

**Raloxifene is an option when bisphosphonates are not tolerated or are contraindicated**

Consider raloxifene, a selective oestrogen-receptor modulator, for postmenopausal women with established osteoporosis who are unable to take bisphosphonates and/or are at high risk of breast cancer. Raloxifene reduces the risk of vertebral fractures but, similar to etidronate and ibandronic acid, it has not shown an effect on non-vertebral fractures<sup>22,23</sup>, and thus is less suitable for women at high risk of hip fracture. In postmenopausal women with osteoporosis and a previous fracture, raloxifene reduced the relative risk of a radiographically detected vertebral fracture by about 30% over 3 years (absolute risk over 3 years was 14.7% with raloxifene vs 21.2% with placebo, NNT = 15).<sup>23</sup> The added advantage of raloxifene is that it may protect against breast cancer. Over 8 years, raloxifene reduced the relative hazard of invasive oestrogen receptor-positive breast cancer by 76% (0.8 cases per 1000 woman-years with raloxifene vs 3.2 cases per 1000 woman-years with placebo).<sup>24</sup>

The advantages of fracture and breast cancer risk reduction with raloxifene need to be weighed against the increased risk of thromboembolic disorders for individual women. Raloxifene is associated with a 3-fold increased risk of venous thromboembolism.<sup>23</sup> In a study of the effect of raloxifene on breast cancer and coronary events, the absolute risk reduction over 5.6 years for invasive breast cancer with raloxifene (1.2 per 1000 woman-years) was largely offset by an increased absolute risk of venous thromboembolism (1.2 per 1000 woman-years) and fatal stroke (0.7 per 1000 woman-years) compared with placebo.<sup>25</sup>

Raloxifene is contraindicated in women at high risk of venous thromboembolism, such as those who are immobilised for long periods. Other side effects such as hot flushes and leg cramps are common and could offset the benefits in some women.<sup>23</sup>



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**Strontium is another option for women who are unable to take bisphosphonates**

Strontium ranelate is an oral form of strontium (not radioactive) that has recently been listed on the PBS for osteoporosis. Strontium reduces the risk of vertebral and non-vertebral fractures<sup>26</sup> and provides an alternative for women who are unable to take bisphosphonates. The efficacy of strontium in reducing hip fractures has not been sufficiently established.<sup>26</sup> Strontium is also a suitable alternative to raloxifene in postmenopausal women at risk of non-vertebral fractures and who are not considered at high risk of breast cancer.

In postmenopausal women with established osteoporosis, strontium reduced the relative risk of a new radiographically detected vertebral fracture over 3 years by about 40% (absolute risk 20.9% vs 32.8% with placebo, NNT = 8).<sup>27</sup> and the relative risk of non-vertebral fractures by 16% (absolute risk 11.2% vs 12.9% with placebo).<sup>28</sup>

Strontium was well tolerated in clinical trials but has been associated with an increased annual incidence of venous thromboembolism (0.9% vs 0.6% with placebo).<sup>29</sup> The long-term safety and efficacy of strontium remain unknown.

Advise women to take strontium at bedtime, at least 2 hours after food, calcium-containing products or antacids.<sup>21</sup>

For more information see *NPS RADAR: Strontium ranelate (Protos) for secondary prevention in postmenopausal osteoporosis* (available at: [www.npsradar.org.au/npsradar/content/strontium.html](http://www.npsradar.org.au/npsradar/content/strontium.html)).

**What is the role of hormone replacement therapy?**

Hormone replacement therapy (HRT) should not be prescribed for the sole purpose of reducing the risk of osteoporotic fracture.<sup>21,30</sup> The primary role of HRT is for short-term control (up to 5 years) of moderate to severe menopausal symptoms<sup>21</sup>, with fracture prevention as a secondary benefit.

The increased risk of coronary heart disease, breast cancer, thromboembolic events and stroke associated with the use of HRT is likely to outweigh the benefits for reducing fracture risk.<sup>2,3,31,32</sup>

**Address other modifiable risk factors**

Drug therapy may not modify certain risk factors for fracture, such as falls.<sup>33</sup>

Use other interventions with osteoporotic drug therapy to help reduce fracture risk, such as smoking cessation, reduced alcohol intake, appropriate exercise and fall-prevention strategies.<sup>3</sup> Ensure an adequate daily intake of calcium and vitamin D and use supplements for people unable to otherwise meet recommended daily intake.<sup>3</sup>

## Ensure sufficient vitamin D and calcium in prevention and treatment of osteoporosis

**How much vitamin D is enough?**

The recommended daily intake of vitamin D varies with age:

- Children and adolescents: 200 IU (5 micrograms) daily
- Adults ≤ 50 years: 200 IU (5 micrograms) daily
- Adults 51–70 years: 400 IU (10 micrograms) daily
- Adults > 70 years: 600 IU (15 micrograms) daily
- Adults at high risk of deficiency: 800 IU (20 micrograms) daily (see over).<sup>9</sup>

Screen for vitamin D deficiency in those at risk due to inadequate sunlight exposure, especially the elderly and housebound or institutionalised people.<sup>9</sup> Provide supplements, in conjunction with adequate calcium, for those unable to achieve adequate sun exposure.

**Prescribe high-dose supplements in vitamin D deficiency**

Treat moderate-to-severe vitamin D deficiency (serum 25-hydroxyvitamin D [25-OHD] level < 25 nmol/L) with high-dose vitamin D supplements (3000–5000 IU/day). Continue high-dose treatment for 6–12 weeks, then reduce to 1000 IU/day thereafter.<sup>9,10</sup> Cholecalciferol (vitamin D<sub>3</sub>) is available as a single ingredient vitamin supplement in 1000 IU formulations. Ergocalciferol (vitamin D<sub>2</sub>) is only available in over-the-counter vitamin and mineral supplements and may be less effective than cholecalciferol in elevating serum 25-OHD levels.<sup>21</sup> Calcitriol is inappropriate for the treatment of vitamin D deficiency.<sup>9,21</sup>

**Use calcium and vitamin D supplements for elderly people in residential care**

In elderly institutionalised women with inadequate calcium and/or vitamin D intake, supplementation with calcium 450–1200 mg/day and cholecalciferol (vitamin D<sub>3</sub>) 700–800 IU/day has been shown to reduce the risk of hip and other non-vertebral fractures compared with placebo.<sup>34,35</sup>

Calcium must be used with vitamin D, and both need to be used with drug therapy for osteoporosis: either alone is insufficient to prevent fractures in people with adequate intakes and those who have already had a fracture.

## Optimise patient compliance with bisphosphonates to achieve fracture risk reduction

**Long-term compliance with bisphosphonate therapy is necessary to minimise the risk of fracture**

Compliance with long-term osteoporotic therapy is often poor.<sup>36,37</sup> Incorrect or inconsistent use, or early discontinuation of osteoporotic therapy can reduce gains in bone mass and increase fracture risk.<sup>38,39</sup>

Common reasons for non-compliance include dosing inconvenience (having to stay upright) and adverse effects. Other factors include a lack of awareness of treatment benefits and the length of time to remain on treatment.<sup>39</sup>

**Check compliance with drug therapy regularly**

Ask patients about their compliance with drug therapy using open questioning (e.g. have you ever missed any of your tablets?).<sup>40–42</sup>

Motivate patients to stay on treatment by highlighting the benefits of persistence rather than the negative consequences of stopping treatment early.<sup>39</sup> Reiterate the purpose and likely duration of treatment. When needed choose medications with less frequent dosing regimens to reduce inconvenience<sup>37</sup>, but encourage proper use to reduce side effects regardless of the bisphosphonate or dosing regimen used. Ask patients if they are having any side effects and provide information (e.g. consumer medicine information) about how they can be prevented or reduced.

## Use bisphosphonates carefully to avoid adverse effects

**Prevent gastrointestinal effects by proper administration**

Correct dosing of bisphosphonates optimises bioavailability and reduces the risk of adverse gastrointestinal effects.<sup>21</sup> Instruct patients to take bisphosphonates early in the morning (with the exception of etidronate, which can be taken at bedtime) on an empty stomach. The medication must be swallowed whole (not crushed, chewed or sucked) with a full glass of water, and the patient must remain upright for 30 minutes to 1 hour after the dose to prevent adverse gastrointestinal effects such as dyspepsia, abdominal pain and oesophageal ulceration.<sup>21,31</sup>

Advise patients not to consume any food or any other drink for at least 30 minutes after alendronate or risedronate (2 hours for etidronate and 1 hour for ibandronic acid). Avoid taking other medications (antacids, calcium, iron and mineral supplements) for 30 minutes after alendronate (2 hours for risedronate and etidronate and 1 hour for ibandronic acid) to allow absorption.<sup>21,31</sup>

## Osteonecrosis of the jaw is a rare complication of bisphosphonate therapy

Bisphosphonate-induced osteonecrosis of the jaw is rare but serious and difficult to treat. Most cases have occurred in patients with multiple myeloma or metastatic cancer treated with intravenous bisphosphonates.<sup>43</sup> Although less common, some cases have been reported with oral bisphosphonates for osteoporosis.<sup>43</sup>

To reduce the risk of osteonecrosis of the jaw, check that all patients (including those with dentures), have had a recent dental health assessment and that all necessary dental treatment has been completed before starting bisphosphonate therapy.<sup>44,45</sup>

- Advise patients about how they can maintain good oral hygiene during treatment and when possible recommend regular dental check-ups. Advise patients with dentures to use soft liners or leave dentures out altogether.
- Advise patients and carers that the risk of osteonecrosis of the jaw is small, but to report any signs and symptoms (including oral pain or soreness, loose teeth or exposed bone) without delay.
- Examine the oral cavity regularly and refer to a dentist if osteonecrosis of the jaw is suspected.<sup>43-45</sup>

Whether or not bisphosphonate therapy should be withheld before dental surgery or once osteonecrosis develops, has not been established. There are anecdotal reports of complete resolution after bisphosphonates were withdrawn for several months.<sup>43</sup>

## Expert reviewer

Professor Leon Flicker

President, Australian Society for Geriatric Medicine (ASGM)

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*The information contained in this material is derived from a critical analysis of a wide range of authoritative evidence. Any treatment decisions based on this information should be made in the context of the clinical circumstances of each patient.*



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