

**TABLE. DRUGS AVAILABLE IN AUSTRALIA FOR THE MANAGEMENT OF OSTEOPOROSIS\*** *continued on next page*

Drug name	Dosage	Fracture reduction	Current PBS indication	Side effects	Clinical practice points
<b>Bisphosphonates</b>					
Alendronate	70 mg weekly oral	VF: 50% HF: 51–56% NVF: 20–35%	<ul style="list-style-type: none"> <li>• Treatment for OP<sup>†</sup></li> <li>• Previous fracture<sup>†</sup></li> <li>• Corticosteroid-induced OP<sup>§</sup></li> </ul> <i>(Streamlined authority for combination with calcium or vitamin D required for all three indications)</i>	<ul style="list-style-type: none"> <li>• Oesophagitis (reduced with enteric-coated tablets)</li> <li>• Musculoskeletal symptoms</li> <li>• Rare: ONJ, AFF</li> </ul>	<ul style="list-style-type: none"> <li>• Check before treating that patient's serum 25-hydroxyvitamin D level is adequate</li> <li>• Caution in renal impairment</li> <li>• To improve absorption, tablets should be taken on an empty stomach, sitting upright, 30 minutes before any other food or drink (unless using the enteric-coated risedronate tablets)</li> </ul>
Risedronate	35 mg weekly oral or 150 mg monthly oral	VF: 41–49% HF: 30% NVF: 33–40%	<ul style="list-style-type: none"> <li>• Treatment for OP<sup>†</sup></li> <li>• Previous fracture<sup>†</sup></li> <li>• Corticosteroid-induced OP<sup>§</sup></li> </ul> <i>(Streamlined authority for combination with calcium or vitamin D required for the above three indications)</i> <ul style="list-style-type: none"> <li>• Preservation of BMD<sup>  </sup></li> </ul> <i>(Authority required)</i>		
Zoledronic acid	5 mg yearly intravenous	VF: 70% HF: 41% NVF: 25%	<ul style="list-style-type: none"> <li>• Treatment for OP<sup>†</sup></li> <li>• Previous fracture<sup>†</sup></li> <li>• Corticosteroid-induced OP<sup>§</sup></li> </ul> <i>(Streamlined authority required for all three indications)</i>		
<b>Oestrogens and oestrogen-related therapy</b>					
Raloxifene	60 mg daily oral	VF: 30–35% NVF: NS	<ul style="list-style-type: none"> <li>• Previous fracture<sup>‡</sup></li> </ul> <i>(Streamlined authority required)</i>	<ul style="list-style-type: none"> <li>• Venous thromboembolism</li> <li>• Exacerbation of menopausal symptoms</li> <li>• Leg cramps</li> <li>• Nausea</li> </ul>	<ul style="list-style-type: none"> <li>• Reduction in risk of breast cancer</li> </ul>
<b>Menopausal hormone therapy</b>					
Combined oestrogen and progesterone	–	VF: 35% <sup>¶</sup> HF: 33% <sup>¶</sup> Peripheral: 29% <sup>¶</sup> Total: 24% <sup>¶</sup>	<ul style="list-style-type: none"> <li>• Not PBS-listed for fracture prevention</li> </ul>	<ul style="list-style-type: none"> <li>• Venous thromboembolism</li> <li>• Increased risk of breast cancer</li> <li>• Cardiovascular disease and stroke</li> </ul>	<ul style="list-style-type: none"> <li>• Consider in perimenopause or early menopause</li> <li>• Progesterone to be added if the woman has an intact uterus</li> </ul>
Oestrogen alone	–	VF: 38% <sup>**</sup> HF: 39% <sup>**</sup> Total: 30% <sup>**</sup>			
Tibolone	1.25 mg daily oral	VF: 45% NVF: 26%	<ul style="list-style-type: none"> <li>• Not PBS-listed for fracture prevention</li> </ul>	<ul style="list-style-type: none"> <li>• Increased stroke in patients &gt; 60 years of age</li> </ul>	<ul style="list-style-type: none"> <li>• Reduction in risk of breast and colon cancer</li> <li>• Benefits other menopausal symptoms</li> </ul>

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Drug name	Dosage	Fracture reduction	Current PBS indication	Side effects	Clinical practice points
<b>Biologic</b>					
Denosumab	60 mg six-monthly subcutaneous	VF: 68% HF: 40% NVF: 20%	<ul style="list-style-type: none"> <li>• Treatment for OP<sup>†</sup></li> <li>• Previous fracture<sup>‡</sup></li> </ul> <i>(Streamlined authority required for both indications)</i>	<ul style="list-style-type: none"> <li>• Cellulitis or skin reaction</li> <li>• Hypocalcaemia</li> <li>• Rare: ONJ, AFF</li> </ul>	<ul style="list-style-type: none"> <li>• Check before treating that patient's serum 25-hydroxyvitamin D level is adequate</li> <li>• Strict six-monthly dosing</li> </ul>
<b>Anabolic</b>					
Teriparatide	20 µg daily subcutaneous	VF: 65% HF: NS NVF: 35%	<ul style="list-style-type: none"> <li>• Treatment for severe OP<sup>††</sup></li> </ul> <i>(Authority required)</i>	<ul style="list-style-type: none"> <li>• Nausea</li> <li>• Leg cramps</li> <li>• Skin reactions</li> <li>• Rare: hypercalcaemia, osteosarcoma</li> </ul>	<ul style="list-style-type: none"> <li>• Total lifetime exposure limited to 18 months in Australia</li> <li>• Consolidation with antiresorptive agent at conclusion of treatment</li> </ul>

Abbreviations: AFF = atypical femoral fracture; HF = hip fracture; NS = not significant; NVF = nonvertebral fracture; ONJ = osteonecrosis of the jaw; OP = osteoporosis; VF = vertebral fracture.

\* All treatments are approved for single-agent use only in Australia.

<sup>†</sup> BMD T-score ≤-2.5 and over 70 years of age. For zoledronic acid, BMD criteria is BMD T-score ≤-3.0.

<sup>‡</sup> Fracture documented on plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

<sup>§</sup> Patient must be on long-term (at least three months), high-dose (at least 7.5 mg daily prednisolone or equivalent) corticosteroid therapy and BMD T-score ≤-1.5.

<sup>||</sup> Patient must be on long-term (at least three months), high-dose (at least 7.5 mg daily prednisolone or equivalent) corticosteroid therapy and BMD T-score ≤-1.0.

<sup>¶</sup> Fracture reduction from trials using conjugated equine oestrogen 0.625 mg daily and medroxyprogesterone acetate 2.5 mg daily.

<sup>\*\*</sup> Fracture reduction from trials using conjugated equine oestrogen at 0.625 mg daily.

<sup>††</sup> BMD T-score ≤-3.0 and patient has had two or more minimal trauma fractures and at least one symptomatic new fracture after 12 months continuous therapy with an antiresorptive agent at adequate doses. Specialist endocrinology or consultant physician input required.