New drugs

Some of the views expressed in the following notes on newly approved products should be regarded as tentative, as there may have been little experience in Australia of their safety or efficacy. However, the Editorial Committee believes that comments made in good faith at an early stage may still be of value. As a result of fuller experience, initial comments may need to be modified. The Committee is prepared to do this. Before new drugs are prescribed, the Committee believes it is important that full information is obtained either from the manufacturer's approved product information, a drug information centre or some other appropriate source.

Teriparatide

Fortéo (Eli Lilly)

3 mL cartridges containing 250 microgram/mL

Approved indication: osteoporosis

Australian Medicines Handbook section 10.3

Teriparatide is a chain of 34 amino acids in a sequence which is identical to the biologically active section of parathyroid hormone. The molecule is assembled by genetically engineered *Escherichia coli*.

Human parathyroid hormone regulates the concentration of calcium in extracellular fluid. It also regulates bone metabolism and acts on the kidney to increase tubular reabsorption of calcium and phosphate.

Although parathyroid hormone increases the release of calcium from bone, intermittent use stimulates osteoblasts more than osteoclasts. By mimicking this effect of parathyroid hormone, teriparatide aims to stimulate bone formation in patients with osteoporosis.

Patients use a pen injector to inject teriparatide subcutaneously once a day. Each cartridge contains enough teriparatide for one month's treatment. Teriparatide has a short half-life of approximately 60 minutes and is undetectable in the serum within three hours. The serum calcium concentration increases two hours after the injection, but returns to normal after 16–24 hours. Teriparatide is probably eliminated by the same mechanism as parathyroid hormone.

There have been several trials of parathyroid hormone in men and women with osteoporosis.[1] One study involved 1637 postmenopausal women who were treated for a median of 19 months. Compared to patients taking vitamin D and calcium, the women who also took teriparatide had fewer fractures. Vertebral fractures occurred in 5% and non-vertebral fragility fractures in 2.6%, compared to 14% and 5.5% in the placebo group.[2]

Another trial studied 34 postmenopausal women with osteoporosis who were taking hormone replacement therapy. Adding recombinant parathyroid hormone resulted in increased bone density and a reduced number of vertebral fractures.[3] Teriparatide also increases bone density in the lumbar spine of men with primary or hypogonadal osteoporosis.

Many patients with osteoporosis are treated with drugs which reduce bone resorption. A trial has therefore compared teriparatide with alendronate. The 146 postmenopausal women in the trial were treated for a median of 14 months. At the one year point alendronate had increased the bone density of the lumbar spine by 5.9% while teriparatide had increased it by 14.2%. Non-vertebral fractures occurred in 13.7% of the alendronate group and 4.1% of the teriparatide group.[4]

In clinical trials of teriparatide 7.1% of patients stopped treatment because of adverse effects. Common adverse effects include nausea, dizziness, asthenia, arthralgia, pain and reactions at the injection site. Some patients develop postural hypotension following the injection. As teriparatide can increase calcium concentrations caution is needed in patients with urolithiasis.

Teriparatide has been associated with osteosarcoma in rats, so it should not be used for more than 18 months. Until more data are available teriparatide should only be prescribed for patients who have a high risk of fractures and cannot take other treatments for osteoporosis.

References

1. Crandall C. Parathyroid hormone for treatment of osteoporosis. Arch Intern Med 2002;162:2297-309.
2. Neer RM, Arnaud CD, Zanchetta JR, Prince R, Gaich GA, Reginster JY, et al. Effect of parathyroid hormone (1-34) on fractures and bone mineral density in postmenopausal women with osteoporosis. N Engl J Med 2001;344:1434-41.
3. Lindsay R, Nieves J, Formica C, Henneman E, Woelfert L, Shen V, et al. Randomised controlled study of effect of parathyroid hormone on vertebral-bone mass and fracture incidence among postmenopausal women on oestrogen with osteoporosis. Lancet 1997;350:550-5.
4. Body JJ, Gaich GA, Scheele WH, Kulkarni PM, Miller PD, Peretz A, et al. A randomized double-blind trial to compare the efficacy of teriparatide (recombinant human parathyroid hormone (1-34)) with alendronate in postmenopausal women with osteoporosis. J Clin Endocrinol Metab 2002;87:4528-35.

NEW FORMULATION

Amoxycillin trihydrate

Maxamox (Sandoz)

500 mg/5 mL powder for oral suspension in 100 mL bottles

NEW STRENGTHS

Citalopram

Celapram (Alphapharm)

10 mg and 40 mg tablets

Clozapine

Clopine (Mayne Pharma)

50 mg and 200 mg tablets

Conjugated oestrogens and medroxyprogesterone acetate

Premia Low (Wyeth)

tablets containing 0.45 mg conjugated oestrogens/1.5 mg medroxyprogesterone acetate

Oxycodone hydrochloride USP

OxyContin (Mundipharma)

5 mg tablets

NEW PROPRIETARY BRANDS

Cefaclor monohydrate

Aclor (Arrow)

125 mg/mL and 250 mg/mL granules for suspension

Diclofenac sodium

Clonac (Arrow)

50 mg tablets

Isosorbide mononitrate

Arsorb (Arrow)

60 mg tablets

Metoprolol tartrate

Metrol (Arrow)

100 mg tablets

Mirtazepine

Axit (Alphapharm)

30 mg tablets

Answers to self-test questions

1. True
2. False
3. False
4. False
5. False
6. False

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