Boniva®: once-monthly oral treatment for postmenopausal osteoporosis

Approved indication

Boniva® 150 mg tablets contain 150 mg ibandronic acid (ibandronate) per tablet. The tablets are indicated for the treatment of osteoporosis in postmenopausal women in order to reduce the risk of vertebral fractures.1

Mode of action

Ibandronic acid is a bisphosphonate and acts selectively on bone tissue, specifically inhibiting osteoclast activity without directly affecting bone formation.1 Bisphosphonates have been shown to reduce bone turnover, improve bone mineral density (BMD) and reduce the risk of fractures in women with postmenopausal osteoporosis.2 Bisphosphonates may be divided into two classes; the low-potency non-nitrogen-containing bisphosphonates and the potent nitrogen-containing bisphosphonates.3 Ibandronic acid belongs to the potent, nitrogen-containing group of bisphosphonates.1 The high-potency profile of ibandronic acid permits its increased dosing interval compared to other oral bisphosphonates which are administered once daily or once weekly.4

Dosage

The recommended dose is one 150 mg tablet once a month. The tablet should preferably be taken on the same date each month.1

Evidence of efficacy

The currently available monthly oral ibandronic acid regimen was approved based on the two-year Monthly Oral Ibandronate in Ladies (MOBILE) trial.4 At two years, substantial increases in lumbar spine BMD were observed in the once-monthly ibandronate group (6.6%).4,5 Substantial increases in proximal femur (total hip, femoral neck and trochanter) BMD were also seen.5 BMD increases achieved in the two-year core study were maintained in the long-term extension of the MOBILE study, with further small gains in lumbar spine BMD over five years.6

Once-monthly 150 mg oral ibandronate has also been shown to be clinically comparable to weekly alendronate at increasing BMD at both the lumbar spine and total hip.7

Precautions

General

Hypocalcaemia must be corrected before therapy is commenced. Other disturbances of bone and mineral metabolism should also be treated before starting treatment. Patients should receive adequate supplemental calcium and vitamin D during treatment.1

Pregnancy and lactation

Boniva® should not be used during pregnancy and lactation.1

Major adverse effects

Monthly treatment with ibandronate 150 mg has been shown to be well tolerated for up to five years in women with postmenopausal osteoporosis, with no new safety signals reported.6 The most common adverse effects reported affected the upper gastrointestinal system, and included dyspepsia, nausea, abdominal pain and diarrhoea.1,4 Transient, influenza-like symptoms have also been reported, typically in association with the first dose.1 These symptoms were generally of short duration, mild to moderate in intensity, and resolved with continued treatment, without requiring remedial measures.1

Drug interactions

The oral bioavailability of Boniva® is generally reduced in the presence of food.1 In particular, products containing calcium and other multivalent cations, such as aluminium, magnesium and iron, including milk, are likely to interfere with the absorption of Boniva®.1 Calcium supplements, antacids and oral medicinal products containing multivalent cations are also likely to interfere with the absorption of Boniva®. Therefore, patients should not take other oral medicine for at least six hours before taking Boniva®, and for one hour after taking it.1

Patient information

In order to maximise absorption of the medicine, the Boniva® tablet should be taken after an overnight fast of at least six hours, and one hour before the first food or drink (other than water) of the day.1
In order to lessen the risk of gastrointestinal irritation, it should be swallowed whole with a glass of plain water while the patient is sitting or standing, and in an upright position. The patient must not lie down for one hour after taking the tablet.1

Conclusion

Once-monthly 150 mg oral ibandronic acid provides an effective therapeutic option for women with postmenopausal osteoporosis.4 The availability of a less frequent bisphosphonate dosing regimen may improve patient satisfaction and adherence to osteoporosis treatment, which could improve the outcomes of therapy for women with postmenopausal osteoporosis.4

References