



Therapeutic Class ReviewSM

ibandronate (Boniva[®]) [Roche/GlaxoSmithKline]

July 2005

New Product for Review:

ibandronate (Boniva[®]) - Roche and GlaxoSmithKline

Dossier Provided by Manufacturer: Yes

Available Therapeutic Alternatives:

Preferred/Formulary	Non-Preferred/Non-Formulary
alendronate (Fosamax [®]) [Merck & Co, Inc.]	
risedronate (Actonel [®]) [Aventis and Procter & Gamble]	

Executive Summary

Boniva 150 mg Once Monthly

- There is **no** evidence that Boniva 150 mg taken once a month:
 - decreases the risk of new vertebral fractures or hip fractures in postmenopausal women with osteoporosis.
 - is superior in safety or efficacy to other oral bisphosphonates (Actonel and Fosamax).

Boniva 2.5 mg Daily (NOTE: this dosage form is not available in the U.S.)

- The evidence is uncertain regarding the benefit of Boniva 2.5 mg daily in reducing bone loss from the lumbar spine in postmenopausal women with osteopenia over a 2-year period when compared to placebo. [Prevention trials]
- The evidence is possibly useful (Grade B) that Boniva 2.5 mg daily may prevent new vertebral fractures in postmenopausal women with osteoporosis over a 3-year period when compared to placebo. [Treatment trial]

Safety

- Harms or potential harms from clinical trials with Boniva may include dyspepsia, diarrhea, and extremity and/or back pain and may include other risks as long-term data become available.
- Although Boniva offers the convenience of once-a-month dosing, there is no evidence that adherence to the monthly regimen is superior to a once-a-week Actonel or Fosamax regimen.

Conclusion

Ibandronate (Boniva) is non-preferred/non-formulary because there is no evidence that the once monthly preparation demonstrates increased clinical benefits or adherence over available alternatives.

Products

Drug Product	Date of FDA Approval	FDA Approved Indications	Dose/Route	AWP Cost* (annual)	Potential Off-Label Uses
alendronate (Fosamax®) ^{1,4}	9/1995 (daily) 10/2000 (weekly)	■ Prevention of osteoporosis in postmenopausal women (PMW)	5 mg p.o. daily OR 35 mg p.o. weekly	\$1047.22 \$1044.55	osteoporosis in Crohn's disease; juvenile osteoporosis; treatment of osteoporosis secondary to organ transplantation
		■ Treatment of osteoporosis in postmenopausal women	10 mg p.o. daily OR 70 mg p.o. weekly	\$1047.22 \$1044.55	
		■ Increase bone mass in men with osteoporosis	10 mg p.o. daily OR 70 mg p.o. weekly	\$1047.22 \$1044.55	
		■ Treatment of glucocorticoid-induced osteoporosis in men and women	5 mg p.o. daily OR 10 mg p.o. daily if PMW not on estrogen	\$1047.22 \$1047.22	
		■ Paget's disease in men and women	40mg p.o. daily x 6mo	\$1164.48	
ibandronate (Boniva®) ^{2,4}	5/2003 (daily) 3/2005 (monthly)	■ Prevention of osteoporosis in postmenopausal women (PMW)	150 mg p.o. monthly	\$964.20	treatment of osteoporosis secondary to organ transplantation; osteoporosis in Crohn's disease; glucocorticoid-induced osteoporosis; Paget's disease; treatment of osteoporosis in men
		■ Treatment of osteoporosis in postmenopausal women	150 mg p.o. monthly	\$964.20	
risedronate (Actonel®) ^{3,4}	3/1998 (daily) 5/2002 (weekly)	■ Prevention of osteoporosis in postmenopausal women (PMW)	5 mg p.o. daily OR 35 mg p.o. weekly	\$1047.31 \$1044.55	treatment of osteoporosis secondary to organ transplantation; osteoporosis in Crohn's disease; juvenile osteoporosis
		■ Treatment of osteoporosis in postmenopausal women	5 mg p.o. daily OR 35 mg p.o. weekly	\$1047.31 \$1044.55	
		■ Treatment and prevention of glucocorticoid-induced osteoporosis in men and women	5 mg p.o. daily	\$1047.31	
		■ Paget's disease in men and women	30 mg p.o. daily x 2mo	\$1205.40	

*AWP (average wholesale price) based on First Data Bank as of May 2005 for one year of therapy or one treatment course, where indicated.

References

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