

New Drug Bulletin:
**Lubiprostone (Amitiza™ - Sucampo
Pharmaceuticals, Inc.)**

September 1, 2006

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Lubiprostone was FDA-approved January 31, 2006 to treat chronic idiopathic constipation in adults. Lubiprostone activates chloride channels in the membrane of gastrointestinal epithelial cells. The result is increased fluid secretion which aids in movement of the bowel.

Lubiprostone is not orally absorbed. It is not metabolized by cytochrome P450 enzymes but is thought to be metabolized by carbonyl reductase in the stomach and jejunum. Lubiprostone is eliminated in the feces. The active metabolite of lubiprostone (M3) is minimally absorbed and achieves a peak concentration after 1.14 hours. M3 has a half-life of 0.9-1.4 hours and is eliminated in the urine and feces.

Two studies evaluated the short-term clinical efficacy of lubiprostone with a primary endpoint of spontaneous bowel movement (SBM) frequency. In the first study, patients taking placebo had a 19% decrease in the number of SBMs at week 4 compared to baseline. Patients in the lubiprostone group had a 180% increase in SBMs at the end of the study. In the second study, patients in the placebo group had a 27% increase in SBMs after four weeks compared to a 215% increase for patients taking lubiprostone. In both studies, patients taking lubiprostone had a SBM sooner than those patients on placebo. There was no rebound effect seen when the patients discontinued the drug after 4 weeks. Three long-term clinical trials studied patients taking lubiprostone over 6-12 months. Patients had decreased constipation and bloating over the course of the study with lubiprostone versus placebo.

The most common adverse events with lubiprostone were nausea (31.1% versus 5.1% for placebo), diarrhea (13.2% versus 0.9%) and abdominal distention (7.1% versus 2.2%). Lubiprostone is minimally absorbed and therefore drug interactions are unlikely.

Lubiprostone is available by prescription only. The recommended dosing regimen is 24 mcg twice daily with food. The drug is manufactured in 24 mcg capsules for oral administration and is supplied in 100-count bottles. The average wholesale price (AWP) is \$291.60 and the wholesale acquisition cost (WAC) is \$243.00 for 100 capsules.

Lubiprostone works in a different way than currently available treatments and is another option for patients with chronic constipation. It does not appear to cause dependence and could be considered in patients who are refractory to other treatments.

References

1. Lubiprostone (Amitiza™) Package Insert. Bethesda MD: Sucampo Pharmaceuticals, Inc. January 2006.