

FDA OKs Amitiza for treatment of IBS-C

April 30 2008

The U.S. Food and Drug Administration announced approval of Amitiza (lubiprostone) to treat constipation associated with irritable bowel syndrome.

The FDA said it approved Amitiza for use by adult women aged 18 and over, making the drug the only FDA-approved treatment for IBS-C available in the United States.

Irritable bowel syndrome is characterized by cramping, abdominal pain, bloating, constipation and diarrhea. It causes a great deal of discomfort and distress to its sufferers, but affects at least twice as many women as men.

"For some people IBS can be quite disabling, making it difficult for them to fully participate in everyday activities," said Dr. Julie Beitz, director of the FDA's Office of Drug Evaluation III. "This drug represents an important step in helping to provide medical relief from their symptoms."

The efficacy of Amitiza in men wasn't conclusively demonstrated for IBS-C and the drug isn't approved for use by children or men. The FDA said it also approved Amitiza for the treatment of chronic idiopathic constipation.

Amitiza is manufactured by Sucampo Pharmaceuticals of Bethesda, Md., and Takeda Pharmaceuticals America Inc. of Deerfield, Ill.

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