US approves drug for middle-of-the-night insomniacs

November 23 2011

The US Food and Drug Administration, for the first time, approved Wednesday medication specifically designed for those who wake up in the middle of the night and cannot fall back to sleep.

Intermezzo, manufactured by Transcept Pharmaceuticals of California, is a lower-dose formulation of zolpidem, first approved in the United States in 1992 and better known as the insomnia treatment Ambien.

"This is the first time the FDA has approved a drug for this condition," the federal government agency said in a statement.

"Intermezzo should only be used when a person has at least four hours of bedtime remaining. It should not be taken if alcohol has been consumed or with any other sleep aid."

The recommended dose is 3.5 milligrams for men and half that for women, after clinical tests indicated that women cleared zolpidem from their bodies more slowly than men do.

"With this lower dose, there is less risk of a person having too much drug in the body upon waking, which can cause dangerous drowsiness and impair driving," said Robert Temple of the FDA's Center for Drug Evaluation and Research.

Spokesmen for Transcept Pharmaceuticals could not be reached for comment.

(c) 2011 AFP