

Gender-specific sleep aid Intermezzo is approved by the FDA

Transcept Pharmaceuticals, Inc. has received approval of Intermezzo[®], a zolpidem tartrate sublingual tablet, from the US Food and Drug Administration. It is approved for the treatment of insomnia that is characterized by middle of the night awakening followed by difficulty returning to sleep. One key differentiator for Intermezzo[®] is that the dose for women differs from the dose for men.

Zolpidem tartrate was originally approved in 1992 as Ambien[®]. However, Intermezzo[®] is a lower-dose formulation of zolpidem tartrate. The recommended dose of Intermezzo[®] is 1.75 mg for women and 3.5 mg for men, taken once per night, if needed. Women metabolize zolpidem at a lower rate than men, so they typically require a lower dose. FDA officials say Intermezzo[®] offers a safer option than taking a second dose of zolpidem and lessens the risk of having too much drug in the body upon waking.

Intermezzo[®] should not be taken if alcohol or another sleep aid has been consumed. The use of Intermezzo[®] is limited to those who experience the middle of the night awakening with 4 or more hours of bedtime remaining. Common side effects experienced by participants during clinical trials were headache, nausea and fatigue. Serious side effects of Intermezzo[®] include next-day impairment, serious anaphylactic reactions, sleep-driving and other complex behaviors, such as making phone calls and eating food.

Zolpidem tartrate carries a risk for physical dependence and abuse and is classified as a Schedule IV controlled substance by Federal Regulation. No pricing information for Intermezzo[®] is available yet for comparison. Cypress Care Clinical Services does not recommend Intermezzo[®] as a first-line medication choice for insomnia. Zaleplon (Sonata) or Zolpidem (Ambien/Ambien CR) are considered first-line, cost-saving alternatives to Intermezzo[®] for treating insomnia and are endorsed by the Official Disability Guidelines.



References:

Intermezzo package insert. © Transcept Pharmaceuticals, Port Richmond, CA.

Official Disability Guidelines. © Work Loss Data Institute, Encinitas, CA 92024. Accessed November 28, 2011.