

FDA approves new sleeping drug from Merck (Update)

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Merck & Co. Inc. has won federal approval for a new type of sleeping pill designed to help people with insomnia stay asleep.

The tablet, Belsomra, works by temporarily blocking chemicals known as orexins that control the sleep cycle and can keep people awake at night. It's unclear whether the new drug is safer or more effective than older drugs because it was tested against a dummy pill, rather than other sleeping medications.

The Food and Drug Administration approved the drug Wednesday in four different doses for various degrees of insomnia. The agency noted that patients who took the highest dose, 20 milligrams, experienced drowsiness and difficulty driving the next morning.

Doctors should warn patients taking the highest dose against next-day driving or activities that require full concentration, the FDA said. It added that side effects such as next-day drowsiness can be reduced by using the lowest effective dose. Drowsiness is a side effect listed on the labels of all anti-insomnia drugs.

In the last year, the FDA lowered the recommended dosage on Ambien, Lunesta and related drugs based on studies showing a link to driving problems and impaired memory and coordination. The agency cited research showing that the drugs remain in the bloodstream at levels high enough to interfere with activities that require focus and attention.

The FDA is requiring that patients who get the new drug receive a medication guide detailing the drug's potential safety issues, including sleep-walking, sleep-driving and other semi-awake activities.

The agency said it approved Belsomra based on three company studies involving 500 patients that showed people taking it fell asleep faster and spent less time awake compared with people taking a dummy pill.

Like other prescription sleeping drugs, Belsomra is designed to be taken only once per night and only when patients have at least seven hours before they need to wake up.

Shares of Merck & Co. Inc., which is based in Whitehouse Station, New Jersey, rose 82 cents, or 1.4 percent, to close at \$57.85.

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