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Zolpidem Containing Products: Drug Safety Communication – FDA Requires Lower Recommended Doses- Including Ambien, Ambien CR, Edluar, and Zolpimist

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FDA 已核准 zolpidem 產品仿單更改新的建議劑量。FDA 核准原因是因為 zolpidem 會增加次日早晨注意力不集中的危險性。

[Update 05/14/2013]

Today, the U.S. Food and Drug Administration (FDA) is notifying the public that FDA has approved label changes specifying new dosing recommendations for zolpidem products (Ambien, Ambien CR, and Edluar), which are widely prescribed sleep medications. FDA has approved these changes because of the known risk of next-morning impairment with these drugs.

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FDA建議降低zolpidem的睡前劑量，因為新的資料顯示：有些患者在使用zolpidem後的隔日早晨，藥物血中濃度仍高到足以影響生活，例如駕駛。本次公告之品項為：核准用於睡前之Zolpidem產品，包含學名藥以及原廠藥Ambien、Ambien CR、Edluar、Zolpimist。

FDA還提醒大家，所有安眠藥物在睡前使用，均可能影響次日早晨的駕駛與活動。所有安眠藥的仿單已將嗜睡列為常見副作用，並警告患者可能會在用藥後的第二天仍然感到昏昏欲睡。即使使用患者認為自己在早晨已經完全清醒，但其注意力仍未完全恢復。

資料顯示，長效劑型的zolpidem，如Ambien CR 和其他學名藥，會增加次日早晨注意力不集中的危險性。尤其以女性更容易有此風險，因為女性代謝zolepidem的速度較男性慢。

FDA要求原廠藥Ambien、Ambien CR、Edluar、Zolpimist，降低建議劑量。

建議

FDA敦促醫療人員提醒所有的患者(男性和女性)，使用安眠藥有可能降低隔日早晨的注意力。

- 女性建議劑量：速效劑型Ambien, Edluar, and Zolpimist，劑量從10 mg降為5 mg；長效劑型Ambien CR，劑量從12.5 mg降為6.25 mg
- 所有的安眠藥品應根據病患症狀使用最低有效劑量。
- 醫療人員應告知患者，即使認為自己在隔日早晨已經完全清醒，但其注意力仍未完全恢復。
- Intermezzo為低劑量的zolpidem產品，核准用於middle-of-the-night awakenings。Intermezzo建議劑量不需改變，因為2011年11月核准時，其仿單建議劑量已標示女性比男性低。

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AUDIENCE: Family Practice, Health Professional, Patient

ISSUE: FDA is notifying the public of new information about zolpidem, a widely prescribed insomnia drug. FDA recommends that the bedtime dose be lowered because new data show that blood levels in some patients may be high enough the morning after use to impair activities that require alertness, including driving. This announcement focuses on zolpidem products approved for bedtime use, which are marketed as generics and under the brand names Ambien, Ambien CR, Edluar, and Zolpimist.

FDA is also reminding the public that all drugs taken for insomnia can impair driving and activities that require alertness the morning after use. Drowsiness is already listed as a common side effect in the drug

labels of all insomnia drugs, along with warnings that patients may still feel drowsy the day after taking these products. Patients who take insomnia drugs can experience impairment of mental alertness the morning after use, even if they feel fully awake.

For zolpidem products, data show the risk for next-morning impairment is highest for patients taking the extended-release forms of these drugs (Ambien CR and generics). Women appear to be more susceptible to this risk because they eliminate zolpidem from their bodies more slowly than men.

Because use of lower doses of zolpidem will result in lower blood levels in the morning, FDA is requiring the manufacturers of Ambien, Ambien CR, Edluar, and Zolpimist to lower the recommended dose.

FDA is continuing to evaluate the risk of impaired mental alertness with other insomnia drugs, including over-the-counter (OTC) drugs available without a prescription.

BACKGROUND: Zolpidem is a sedative-hypnotic (sleep) medicine used in adults for the treatment of insomnia. It is marketed as generics and under the brand-names Ambien, Ambien CR, Edluar, Zolpimist, and Intermezzo.

RECOMMENDATION: FDA urges health care professionals to caution all patients (men and women) who use these products about the risks of next-morning impairment for activities that require complete mental alertness, including driving.

- The recommended dose of zolpidem for women should be lowered from 10 mg to 5 mg for immediate-release products (Ambien, Edluar, and Zolpimist) and from 12.5 mg to 6.25 mg for extended-release products (Ambien CR).
- For zolpidem and other insomnia drugs, prescribe the lowest dose that treats the patient's symptoms.
- Inform patients that impairment from sleep drugs can be present despite feeling fully awake.
- The recommended doses of Intermezzo, a lower dose zolpidem product approved for middle-of-the-night awakenings, are not changing. At the time of Intermezzo's approval in November 2011, the label already recommended a lower dosage for women than for men.