



Safety Information

SI:002/08

19 June 2008

This Safety Information is designed to highlight the risks associated with zolpidem ("stilnox") use as identified by the Therapeutic Goods Administration.

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Directors of Clinical Operations

Expert Reference Group

Content has been reviewed by:

- NSW Therapeutic Advisory Group

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Zolpidem ("Stilnox")

Zolpidem is a sedative medication used for the treatment of insomnia. Up until 4 January 2008 the Therapeutic Goods Administration had received 1,032 reports of incidents involving suspected adverse reactions to zolpidem. 394 of these 1,032 reports presented as abnormal sleep-related behaviour eg. sleep walking, sleep driving. Several of these adverse reactions were considered to have contributed to significant harm.

As a result the Therapeutic Goods Administration has required that a black box warning* is added to the product information for zolpidem. The warning is:

"Zolpidem may be associated with potentially dangerous complex sleep-related behaviours which may include sleep walking, sleep driving and other bizarre behaviours. Zolpidem is not to be taken with alcohol. Caution is needed with other CNS depressant drugs. Limit use to four weeks maximum under close medical supervision."

* A black box warning is a succinct warning statement printed at the start of the approved product information, designed to alert prescribers to an important safety issue with a medicine. The warning is highlighted by a bold black surround or "box".

Hospitalised patients

Sleep walking and other associated behaviours may lead to harm in hospitalised patients through falls and other misadventures.

Steps to minimise risk

Healthcare facilities should consider reviewing their use of zolpidem and:

- Consider removing zolpidem from hospital formularies, or restricting its use
- Exercise particular care in the treatment of elderly patients or those who have been identified to be at risk of falls
- Medical teams to assess the need for, and appropriate use of, zolpidem in their patients admitted on zolpidem
- If prescribed, ensure that administration is timed so that the patient is likely to remain in bed (eg. has gone to the toilet prior to administration)
- If prescribed, monitor patients for possible drug interactions and allergic reactions.

Further Reading

[ADRAC. Zolpidem and bizarre sleep related effects. Aust Adv Drug React Bull February 2007;26\(1\).](#)

[Therapeutic Goods Administration. Media Statement. Medicine regulator places boxed warning on Stilnox. 21 February 2008.](#)

Recommended actions by Area Health Services

1. Forward information to appropriate areas for action.
2. Consider the "steps to minimise risk" set out above.