Safety Information
SI:002/08

19 June 2008

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:

* 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


Recommended actions by Area Health Services

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