

IMPORTANT INFORMATION REGARDING STILNOX[®], STILNOX[®] CR & DORMIZOL[®]: BOXED WARNING

05 March 2008

Dear Healthcare Professional,

Sanofi-aventis australia Pty limited would like to inform you of important regulatory developments that affect Stilnox (zolpidem tartrate) 10mg tablets and Stilnox CR (zolpidem tartrate) modified-release tablets in Australia. The Therapeutic Goods Administration (TGA), has requested that all sponsors of zolpidem introduce a boxed warning (see below) to further reinforce important information that exists in the Product Information (PI) and Consumer Medicine Information (CMI) related to the appropriate use of this medicine:

Product Information

Warning: 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.

Consumer Medicine Information

Warning: Zolpidem may be associated with unusual and potentially dangerous behaviours whilst apparently asleep. These have included sleep walking, driving motor vehicles and other bizarre behaviours. Some medicines may interact with zolpidem and particular caution is needed with other drugs that may also act on the brain; before you take zolpidem refer to the "Taking other medicines" section below or ask your doctor or pharmacist. You must not drink alcohol when you take zolpidem. Do not take zolpidem for more than 4 weeks. If your sleep problems continue, consult your doctor.

A copy of the updated PI for Stilnox CR is included with this letter. The CMI's for Stilnox and Stilnox CR have also been updated and are available from our website (www.sanofi-aventis.com.au). Sanofi-aventis continues to work closely with the TGA to ensure the quality use of this medicine.

The above mentioned changes apply to all brands of zolpidem, including sanofi-aventis' Dormizol[®]. Should you require any further information please do not hesitate to contact our Medical Information Department on 1800 818 806.

Yours sincerely,



Dr Gordon Hirsch
Medical Director