NSW HEALTH PHARMACEUTICAL SERVICES BRANCH

GUIDELINES FOR THE PRESCRIBING OF FLUNITRAZEPAM

In August 2000 flunitrazepam was scheduled as a drug of addiction in New South Wales in line with other States and Territories, due to concern about the harm caused by its misuse. As a result, it may not be prescribed for longer than two months for a non-drug-dependent patient without an authority issued by the NSW Department of Health. In the case of drug-dependent persons, approval prior to prescribing is required.

Flunitrazepam has marketing approval for the treatment of severe insomnia at an adult dose of 1-2mg. A lower dose of 0.5-1mg is indicated in the elderly. As with other benzodiazepines, continuous long-term use is not recommended and, if used at all, should be limited to the shortest time possible and a definite limited duration of use agreed with the patient (two to four weeks maximum is recommended).

For a non-drug-dependent person taking no other drug of addiction, an authority is not required for the short-term use of flunitrazepam for up to two months. However, it should be noted that current best practice in the treatment of insomnia focuses on non-drug measures including behavioural therapy, relaxation techniques, avoidance of stimulant substances and changes in lifestyle that promote good sleeping patterns, with drugs used only when necessary as a short-term adjunct. Referral to an appropriate specialist may be helpful for difficult and complex cases.

Benzodiazepines in general should not be considered as first-line treatment for chronic insomnia. They should only be used as a last resort after non-pharmacological approaches have proved unsuccessful. Flunitrazepam in particular, given its speed of onset of action and greater potential for dependence, is not recommended for the management of chronic insomnia or related anxiety conditions. Furthermore, active metabolites which increase the risk of accumulation of the drug make the use of flunitrazepam of particular concern in the elderly, who may as a result suffer ataxia and consequent falls and injury, confusion, memory loss and cognitive impairment.

A number of studies in Australia and overseas strongly suggest that flunitrazepam is more liable to dependence and abuse than other benzodiazepines due to its rapid onset of action and euphoric effect. It is also more likely than other abused drugs to contribute to heroin and methadone related deaths due to combined drug toxicity.

Due to the high risk of abuse and its potential for harm, flunitrazepam is therefore unsuitable for managing drug withdrawal. Benzodiazepines with a long half-life (usually diazepam) are recommended for drug or alcohol withdrawal because they result in more constant plasma levels over a 24 hour period, less intense withdrawal symptoms, better patient compliance and lower morbidity. Reference should be made to the *NSW Department of Health Detoxification Clinical Practice Guidelines*.

For benzodiazepine dependence, a tapered, supervised withdrawal may require several weeks or months. Where there is polysubstance abuse or dosage has been high, referral to a drug and alcohol treatment service for detoxification is recommended.

RESOURCES

National Health and Medical Research Council (NHMRC), 1999, Guidelines for the Prevention and Management of Benzodiazepine Dependence. Monograph Series No3.

Victorian Drug Usage Advisory Committee, Therapeutic Guidelines: *Psychotropic*, Melbourne, 2000. Available from Therapeutic Guidelines Ltd. Telephone: (03) 9329 1566, facsimile (03) 9326 5632, or freecall 1800 061 260.

NSW Detoxification Clinical Practice Guidelines. NSW Health Department, 1999. Available from Better Health Centre. Telephone: 9816 0452.

Mant, Andrea et al. Anxiety and Insomnia: think twice before prescribing. The Royal Australian College of General Practitioners (RACGP), 1997.

Mant, A. Benzodiazepine Dependence: Strategies for Prevention and Withdrawal. Current Therapeutics, Feb. 1996.

National Prescribing Service Newsletter: Vol. 4, 1999. Includes patient education material on: (i) Getting a good night's sleep (ii) A reduction plan for sleeping tablets and sedatives. Telephone: (02) 9332 3944.

Royal Australian and New Zealand College of Psychiatrists (RANZCP) Practice Guideline #5: College Guidelines for the Use of Benzodiazepines. Internet: www.ranzcp.org/statements/pg/pg5.htm

Recognising and Handling Patients Liable to Abuse Benzodiazepines, Notes for Medical Practitioners (TG 199), 1998. Pharmaceutical Services Branch, NSW Health Dept.

NSW Drug and Alcohol Specialist Advisory Service (24 hour clinical consultancy service for health professionals).

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