

# Alprazolam to become Schedule 8: Information for prescribers

from 1 February 2014

## Purpose of this document

From 1 February 2014, alprazolam will be rescheduled in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) to Schedule 8. The purpose of this document is to inform prescribers of the regulatory requirements for prescribing alprazolam and the clinical guidelines and patient guides available for the treatment of anxiety disorders. This document has been endorsed by the Department of Health's Chief Psychiatrist.

## Indications for use

The approved indications for alprazolam as listed on the Australian Register of Therapeutic Goods are:

- Anxiety: the short-term symptomatic treatment of anxiety including treatment of anxious patients with some symptoms of depression; and
- Panic disorder: the treatment of panic disorder with or without some phobic avoidance, and for blocking or attenuation of panic attacks and phobias in patients who have agoraphobia with panic attacks.

## Policy for the issue of permits to prescribe alprazolam

The legislative requirements in Victoria for prescribers in relation to obtaining Schedule 8 permits will apply with alprazolam when it is rescheduled as a Schedule 8 poison. For a comprehensive summary of requirements for Schedule 8 treatment permits, please refer to the document *Schedule 8 permit requirements plus notification requirements* on the Department of Health website at: <http://www.health.vic.gov.au/dpcs/reghealth.htm>

**Applications for permits to prescribe alprazolam will generally require evidence that recent supportive advice has been obtained from a specialist in a field of specialty relevant to the patient's medical condition for a permit to be issued.**

**Given that alprazolam is indicated for the short-term treatment of anxiety or panic disorder, support from a psychiatrist will be required. In circumstances where there are addiction-related issues with alprazolam, support from an addiction medicine specialist will be required. Without such evidence, applications may be refused.**

## Prior to alprazolam being rescheduled

Between now and 1 February 2014, given that alprazolam is neither approved nor recommended for chronic use, prescribers who have been treating patients with alprazolam long-term should consider alternative treatment options where appropriate. In circumstances where prescribers may consider it necessary for patients to continue treatment with alprazolam, arrangements should be made for patients to obtain specialist reviews in support of their use of alprazolam for an extended period.

It is likely that a growing awareness about the imminent rescheduling of alprazolam will precipitate an increased demand for the drug by those who have been using it appropriately in addition to those who have been misusing, abusing and diverting it. Prescribers are advised not to prescribe quantities or repeat supplies which might enable patients to accumulate inappropriate quantities of alprazolam, noting that the requirement to not prescribe in excess of therapeutic need is mandated under the Drugs, Poisons and Controlled Substances Regulations 2006.

## Reasons for rescheduling

Scheduling decisions on medicines are made by the Secretary of the Commonwealth Department of Health and Ageing and adopted nationally, after consideration of recommendations from an advisory committee and submissions through a public consultation process.

In summary, the reasons for the decision to reschedule alprazolam to Schedule 8 were:

- Alprazolam is associated with increased morbidity and mortality in overdose with possible increased toxicity compared with other benzodiazepines.
- Alprazolam does not appear to have any additional therapeutic benefits compared with any other benzodiazepine.<sup>†</sup>
- Submissions suggested that there has been a rapid increase in use of alprazolam compared with other benzodiazepines and that there is evidence of widespread misuse.
- There is concern that the current pack size of alprazolam is inappropriate for the approved indications, i.e. for short-term use.
- Submissions stated that there is evidence of abuse of alprazolam and misuse with opioids, with it being more subject to diversion from licit to illicit use than with other benzodiazepines.

It was noted that listing in Schedule 8 of alprazolam does not restrict its short-term use for the approved indications.

The full record of reasons plus the summary of submissions for the rescheduling of alprazolam are available on the Therapeutic Goods Administration (TGA) website at: <http://www.tga.gov.au/industry/scheduling-decisions-1306-final.htm>

## Facts on alprazolam related to its inappropriate use

- The high potency and short onset of action of alprazolam makes it a preferred drug for abuse and alprazolam is the most commonly reported benzodiazepine among Australian injecting drug users who report injection of benzodiazepines.<sup>1</sup>
- Alprazolam is more subject to non-medical use compared with other benzodiazepines, and causes a disproportionately high level of serious harm than other benzodiazepines.<sup>2</sup>
- Alprazolam 2mg tablets are often concurrently prescribed for patients for whom other medical practitioners hold permits to prescribe opioid replacement therapy without the knowledge or consent of the permit holders, who also may be prescribing longer-acting benzodiazepines, e.g. diazepam.<sup>3</sup>
- Alprazolam 2mg tablets are the subject of the majority of forged prescription reports in Victoria<sup>4</sup> and have a significant street value.
- Alprazolam contributed to 56 deaths in Victoria in 2010, representing 16.6% of total drug-induced or drug-related deaths investigated by the Coroners Court of Victoria in 2010.<sup>5</sup>
- Inappropriately high doses of alprazolam can cause anterograde amnesia and are associated with anger, aggression plus violent and threatening behaviour, which the subjects do not remember next day.<sup>6</sup>
- Subjects affected by high doses of alprazolam lose inhibition and, if they commit crimes while affected, may be unaware of their surroundings and when they recover in police cells, do not remember the actions that led to their arrest.<sup>7</sup>

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<sup>1</sup> Mumford G, Evans S, Fleishaker J, et al. (1995) Alprazolam absorption kinetics affects abuse liability. *Clinical Pharmacology and Therapeutics* 57:356-365.

<sup>2</sup> Kirwan A et al. (2012) Victorian Drug Trends 2011, Findings from the Illicit Drug Reporting System. Macfarlane Burnet Institute for Medical Research and Public Health & Turning Point Alcohol and Drug Centre, Australian Drug Trends Series No. 76.

<sup>3</sup> Drugs and Poisons Regulation data.

<sup>4</sup> Drugs and Poisons Regulation data.

<sup>5</sup> Coroners Court of Victoria (2012) Finding into death with inquest, Inquest into the Death of David Andrew Trengrove, Delivered on 18 May 2012.

<sup>6</sup> Jones K et al. (2011) A Pinch in Every Bottle: Expert perspectives of alprazolam use and its relationship to offending. Poster presentation, Australasian Professional Society on Alcohol and Other Drugs Conference. 13-16 Nov 2011. Hobart, Australia.

<sup>7</sup> Ibid.

## Further information

### Clinical advice for health professionals

The National Prescribing Service (NPS) recommends that the use of benzodiazepines, including alprazolam, is **not recommended as first line treatment** for anxiety or panic disorder. Benzodiazepine use should be reserved to the short-term for patients who have not responded to at least two other therapies (e.g. psychological therapy, antidepressants).

The NPS fact sheet *NPS News 65 (2009): Anxiety disorders - which treatment for what anxiety disorder?* provides information on evidence-based treatment strategies for anxiety disorders. The fact sheet is available on the NPS website at: <http://www.nps.org.au/publications/health-professional/nps-news/2009/nps-news-65>

A summary of the Royal Australian and New Zealand College of Psychiatrists (RANZCP) *Clinical Practice Guidelines for the treatment of panic disorder and agoraphobia* is available on the RANZCP website at: <http://www.ranzcp.org/Files/ranzcp-attachments/Resources/Publications/CPG/Clinician/APY529-pdf.aspx>

The Drug and Alcohol Clinical Advisory Service (DACAS) has prepared a fact sheet *Withdrawal from benzodiazepine dependence* for information about benzodiazepine withdrawal in a general practice setting. The fact sheet is available at the DACAS website: [http://www.dacas.org.au/Clinical\\_Resources/For\\_GPs.aspx](http://www.dacas.org.au/Clinical_Resources/For_GPs.aspx)

To obtain clinical advice from addiction medicine consultants, health professionals may phone the Drug and Alcohol Clinical Advisory Service (DACAS) on **1800 812 804**.

### Counselling and advice for patients

The RANZCP has developed a guide *Panic disorder and agoraphobia: Australian treatment guide for consumers and carers*. The guide is available on the RANZCP website at: [http://www.ranzcp.org/Files/ranzcp-attachments/Resources/Publications/CPG/Australian\\_Versions/AUS\\_Panic\\_disorder-pdf.aspx](http://www.ranzcp.org/Files/ranzcp-attachments/Resources/Publications/CPG/Australian_Versions/AUS_Panic_disorder-pdf.aspx)

Consumer fact sheets on anxiety disorders and treatment options for anxiety are available on the Better Health Channel website at: [http://www.betterhealth.vic.gov.au/bhcv2/bhcarticles.nsf/pages/Anxiety\\_disorders\\_overview](http://www.betterhealth.vic.gov.au/bhcv2/bhcarticles.nsf/pages/Anxiety_disorders_overview) and [http://www.betterhealth.vic.gov.au/bhcv2/bhcarticles.nsf/pages/Anxiety\\_treatment\\_options](http://www.betterhealth.vic.gov.au/bhcv2/bhcarticles.nsf/pages/Anxiety_treatment_options)

For 24-hour confidential drug and alcohol counselling and treatment information, patients, family or health professionals may phone **DirectLine** on **1800 888 236**.

### Legislative enquiries for health professionals

Health professionals may phone **Drugs and Poisons Regulation (DPR)** on **1300 364 545** or email at: [dpcs@health.vic.gov.au](mailto:dpcs@health.vic.gov.au) for further information about:

- Legislative requirements for the administration, prescribing or supply of alprazolam.
- Schedule 8 permit requirements in relation to alprazolam.
- The department's *Policy for the issue of permits to prescribe Schedule 8 poisons*.

Information is also available on the Department of Health website at: <http://www.health.vic.gov.au/dpcs>

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Authorised by the Victorian Government, Melbourne. To receive this publication in an accessible format phone Drugs and Poisons Regulation on 1300 364 545.

<sup>†</sup> While this statement was made by the Secretary of the Commonwealth Department of Health and Ageing in the Record of Reasons for the rescheduling of alprazolam, the Victorian Department of Health is aware that the half-life and onset of action of alprazolam may provide some benefit over other benzodiazepines for treatment of panic disorder at therapeutic doses. However, its use is limited by the risk of dependency and the high relapse rate on cessation. Refer to the sponsor's Product Information document for further information.