# Alprazolam:
## a Schedule 8 drug of dependence –
### information about the scheduling change effective 1 February 2014

This resource assists health professionals to:

- Be informed about the changes to alprazolam scheduling effective 1 February 2014
- Be aware of their legal obligations and the Drugs of Dependence Unit policy on granting section 18A *Controlled Substances Act 1984* (SA) authorities to prescribe alprazolam
- Prepare for the upcoming change in alprazolam scheduling
  - Be informed about where to obtain clinical advice and further information for themselves, their patients and carers
- Critically examine the need for prescribing alprazolam in their medical practice
  - Consider approved indications for use and evidence based alternatives to alprazolam
- Become familiar with the facts about alprazolam abuse

### Changes to the scheduling of alprazolam effective 1 February 2014

From 1 February 2014 alprazolam will be rescheduled in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) to Schedule 8; it will be classified as a drug of dependence.

### Reasons for the change

The Therapeutic Goods Administration (TGA) made the decision to reschedule alprazolam from a Schedule 4 drug to a Schedule 8 drug after advice from the Advisory Committee on Medicines Scheduling following extensive public consultation.

### The reasons stated by the TGA for the decision to reschedule alprazolam are:

- *Alprazolam has increased morbidity and mortality in overdose with possible increased toxicity. It does not appear to have any additional therapeutic benefits compared with any other substance in the class.*
- *There has also been a rapid increase in use of alprazolam compared with other benzodiazepines and evidence of widespread misuse.*
- *Concerns of possible increased toxicity.*
- *Concern that current pack size is inappropriate for indications.*
- *There is evidence of abuse of the substance and misuse with opioids.*
- *Listing in Schedule 8 of alprazolam does not restrict its short-term use for the approved indication.*

For further information about the reasons for the rescheduling of alprazolam see:
http://www.tga.gov.au/industry/scheduling-decisions-1306-final.htm

### Prescriber legal obligations

As with all drugs of dependence, a registered health practitioner must not prescribe alprazolam for regular use by a person exceeding two months (including when the drug has been prescribed by another practitioner) without a relevant authority* granted by the Drugs of Dependence Unit). A person who the practitioner knows, or has reasonable cause to believe, is dependent on drugs must not be prescribed any drug of dependence, including alprazolam, unless in accordance with an authority.[1]

**Unless specifically exempted by the Regulations, for example, where the patient is 70 years of age or more. For more information about exemptions, refer to Controlled Substances (Poisons) Regulations 2011 (Reg 22).*

Health professionals may phone the Drugs of Dependence Unit on **1300 652 584** or email: drugsofdependenceunit@health.sa.gov.au for more information about their legal obligations. Information is also available via our website www.sahealth.sa.gov.au/drugsofdependence

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### Obtaining an authority to prescribe alprazolam

The legislative requirements in South Australia for obtaining an authority to treat a person with a drug of dependence will apply to alprazolam on 1 February 2014. For an overview of the legislative scheme please refer to www.sahealth.sa.gov.au/drugsofdependence

Authorities to prescribe alprazolam may only be granted with evidence of current support for treatment from a specialist medical practitioner **in the field of specialty relevant to the patient's medical condition for which alprazolam is prescribed**.

For example, given that alprazolam is indicated for the short-term treatment of anxiety or panic disorder, documented support from a psychiatrist detailing the medical need for extended treatment will be required. In circumstances where there are drug related addiction issues, documented support from an addiction specialist will be required, and so on.

Applications for authority made to the Drugs of Dependence Unit that are not accompanied by relevant documented specialist support may not be granted. In assessment of any application, delegates will give consideration to the fact that the ARTG has not approved alprazolam for use for long term treatment of anxiety disorders or for the treatment or maintenance of drug dependence.

## Preparing for the change

Given that alprazolam is not approved or recommended for long term use, medical practitioners who have been treating patients with alprazolam for an extended period should consider alternate treatment options where appropriate. Where practitioners may consider it necessary for patients to continue treatment with alprazolam, arrangements should be made for patients to obtain relevant specialist reviews.

## Clinical advice for health professionals

- Health professionals may obtain clinical advice from the Drug and Alcohol Clinical Advisory Service (DACAS) on **8363 8633**.
- Drug and Alcohol Services SA (DASSA)has produced a guide "**Benzodiazepines: Information for GPs**" which provides a withdrawal regimen and is available at: http://www.dassa.sa.gov.au/webdata/resources/files/Benzodiazepines_-_GPs_2013.pdf
- 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 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

## Counselling and advice for patients

- For telephone counselling and advice contact the Alcohol and Drug Information Service on **1300 13 1340**.
- To find out more about the different treatment options available, consumers and carers may refer to:
  - Panic disorder and agoraphobia, Australian treatment guide for consumers and carers, RANZCP, August 2009 https://www.ranzcp.org/Files/ranzcp-attachments/Resources/Publications/CPG/Australian_Versions/AUS_Panic_disorder-pdf.aspx
  - Beyond Blue: www.beyondblue.org.au **1300 22 4636**

## Information on scheduling and authority matters

Drugs of Dependence Unit **1300 652 584**

## Approved indications for use

*Alprazolam is a rapid-onset, short-acting benzodiazepine indicated for the short term symptomatic treatment of anxiety and panic disorder.*

The approved indications as listed on the Australian Register of Therapeutic Goods (ARTG) are:

*Anxiety:* The short-term symptomatic treatment of anxiety including treatment of anxious patients with some symptoms of depression;

*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.

## Use of alprazolam in panic disorder

Prescribers should exclude from the differential diagnosis a Generalised Anxiety Disorder, Social Phobia, Obsessive-Compulsive Disorder, Post Traumatic Stress Disorder, anxiety symptoms associated with drug misuse, or anxiety due to a general medical condition.[2]

Whilst isolated panic attacks may be common, panic disorder is uncommon and affects 2% - 3% of the population, more common in women (3:1).[3]

The point-prevalence in Australia has been identified as low as 0.7%.[4]

***First-line treatment for panic disorder is with psychological interventions.[3]***

*Education about the disorder, in particular explaining the way in which the panic attack produces physical symptoms, is essential. The breathing control strategies described for panic attack treatment and relaxation strategies are also important first steps.[3]*

*Cognitive behavioural therapy (CBT) is the treatment of choice for panic disorder. There are several versions used for panic disorder. The most commonly used is panic control treatment, which involves exposure to deliberately induced symptoms, together with techniques (such as controlled slow breathing) for controlling symptoms and reattribution of symptoms to benign causes (eg. palpitations are not due to cardiac arrest)."[3]*

When CBT is not available or is ineffective, pharmacological treatment may be considered including:

> selective serotonin reuptake inhibitors (SSRIs) and venlafaxine (regarded as first-line pharmacotherapy)

> tricyclic antidepressants (TCAs)

> irreversible nonselective monoamine oxidase inhibitors (MAOIs)

> some benzodiazepines

> antidepressants are considered the most appropriate long-term pharmacotherapy.[3]

## Facts about alprazolam abuse

> The high potency and short onset of action of alprazolam makes it a preferred drug for abuse.[5]

> Alprazolam is the most commonly reported benzodiazepine among Australian injecting drug users who report injection of benzodiazepines.[5]

> Alprazolam is more subject to non-medical use compared with other benzodiazepines, and causes a disproportionally high level of serious harm than other benzodiazepines.[6]

> Harms related to alprazolam include severe ischaemic limb damage and disability associated with injecting alprazolam, memory blanks acutely and over days, disinhibited and aggressive behaviour and death when used concurrently with opioids.[7]

> Alprazolam is often sought to enhance the high of injected opiates and to ameliorate the 'come down' from amphetamine use or symptoms of opiate withdrawal.[7]

> Patients describe risky behaviours while under the influence of alprazolam that include driving, assaults, drug use, other criminal behaviours or waking up after a period of amnesia and being frightened by what might have happened to them or what they might have done.[8]

> Alprazolam is readily available and relatively cheap; 2 mg alprazolam tablets are the most popular and are easily available on the streets for $3-5 for each tablet.[8] Given that a prescription of 50 alprazolam tablets is relatively inexpensive even without PBS subsidy, the on selling of this prescription drug is lucrative.

> Patients prescribed large amounts without close monitoring, including private prescriptions and repeats without repeat intervals between dispensing, are reported as selling many of their tablets.[7]

## References

The Drugs of Dependence Unit acknowledges and thanks the Victorian Department of Health for the use of their document "Alprazolam to become Schedule 8: Information to Prescribers". Information obtained from the above was used throughout this document.

1. Controlled Substances Act 198, Regulation 18A. http://www.legislation.sa.gov.au/LZ/C/A/CONTROLLED%20SUBSTANCES%20ACT%201984/CURRENT/1984.52.UN.PDF
2. American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders* (DSM-IV-TR), (2003 4th ed), 429 – 484.
3. eTG complete, 'Panic Disorder' (July 2013) Therapeutic Guidelines Limited, http://online.tg.org.au/ip/desktop/index.htm, viewed 2 October 2013.
4. Andrews G, Hall W, Teesson M, and Henderson S, 'The Mental Health of Australians' (1999) Commonwealth Government, Department of Health and Aged Care.
5. Mumford G, Evans S, Fleishaker J, et al. (1995) Alprazolam absorption kinetics affects abuse liability. Clinical Pharmacology and Therapeutics 57:356-365.
6. 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.
7. Dr Barbara Paterson, Chief Health Officer, Department of Health and Families, Northern Territory Government. Letter to all NT General Practitioners and Psychiatrists (3 Dec 2010). http://www.health.nt.gov.au/library/scripts/objectifyMedia.aspx?file=pdf/53/13.pdf&siteID=1&str_title=Advisory%20from%20the%20CHO%202010%20-%20Alprazolam.pdf, viewed 24 September 2013.
8. Therapeutic Goods Administration TGA 2013, Benzodiazepines – submission 31 of 34 (page 11), http://www.tga.gov.au/pdf/submissions/scheduling-submissions-1303-9.pdf, viewed 2 October 2013.

## For more information

**Drugs of Dependence Unit**
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**Telephone: 1300 652 584**
**www.sahealth.sa.gov.au/drugsofdependence**