



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	387290	ALPRAZOLAM SANDOZ alprazolam 1 mg tablet blister pack
<b>ARTG entry for</b>	Medicine Registered	
<b>Sponsor</b>	Sandoz Pty Ltd	
<b>Postal Address</b>	54 Waterloo Road, Macquarie Park, NSW, 2113 Australia	
<b>ARTG Start Date</b>	2/06/2023	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	Drug Safety Evaluation Branch	

**Conditions**

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

### Products

#### 1 . ALPRAZOLAM SANDOZ alprazolam 1 mg tablet blister pack

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	2/06/2023
---------------------	-------------------------	-----------------------	-----------

**Permitted Indications**

No Permitted Indications included on Record

**Indication Requirements**

No Indication Requirements included on Record

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

Anxiety ,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. ,The diagnostic criteria for panic disorder in DSM-III-R are as follows: ,The panic attacks (discrete periods of intense fear or discomfort), at least initially, are unexpected. Later in the course of this disturbance, certain situations (e.g. driving a car or being in a crowded place) may become associated with having a panic attack. These panic attacks are not triggered by situations in which the person is the focus of others' attention (as in social phobia). ,The diagnosis requires four such attacks within a four week period, or one or more attacks followed by at least a month of persistent fear of having another attack. ,The panic attacks must be characterised by at least four of the following symptoms: dyspnoea or smothering sensations; dizziness, unsteady feelings or faintness; palpitations or tachycardia; trembling or shaking; sweating; choking; nausea or abdominal distress; depersonalisation or derealisation; paraesthesiae; flushes (hot flashes) or chills; chest pain or discomfort; fear of dying; fear of going crazy or of doing something uncontrolled. ,Note. Attacks involving four or more symptoms are panic attacks; attacks involving fewer than four are limited symptom attacks. ,At least some of the panic attack symptoms must develop suddenly and increase in intensity within ten minutes of the beginning of the first symptom noticed in the attack. ,The panic attack must not be attributable to some known organic factor, e.g. amphetamine or caffeine, intoxication, hyperthyroidism. ,The efficacy of alprazolam in conditions where the above criteria are not met has not been established. The risk versus benefits of alprazolam use in milder disorders, which do not meet the above criteria, has not been evaluated. Although current evidence supports the long-term clinical effectiveness of alprazolam in panic disorder, the continuing use of alprazolam needs to be weighed against the difficulties that can occur with dependence and discontinuation. ,The results of a long-term study in patients taking alprazolam (ie. beyond three months) suggest that many patients continue to benefit from alprazolam therapy and that alprazolam efficacy is maintained for up to eight months. ,The physician should periodically reassess the usefulness of the drug for each patient. ,A comparative study of alprazolam and placebo in the treatment of panic attacks in patients with panic disorder involved 543 patients over an eight week period. Alprazolam was significantly more effective than placebo in reducing the total number of panic attacks ( $p < 0.0001$ ); at week 4, 46.8 percent of alprazolam patients had achieved zero total panic attacks when compared to 27.1 percent of placebo patients. ,Panic disorders are often severe, chronic illnesses that cause a high level of work and social disability, increased substance abuse and potentially increased morbidity and mortality. ,Psychological and social factors are important in the pathogenesis of panic attacks, either acting alone or in combination with biological factors. Prolonged pharmacological therapy may be used as an adjunct to psychosocial therapy in the treatment of patients with panic disorders.

**Warnings**

See Product Information and Consumer Medicine Information for this product

**Additional Product information**

#### Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Blister Pack	PVC/Al	36 Months	Store below 25 degrees Celsius	Not recorded	Not recorded

Public Summary



Australian Government  
Department of Health and Aged Care  
Therapeutic Goods Administration

**Pack Size/Poison information**

**Pack Size**  
10

**Poison Schedule**  
(S8) Controlled Drug

**Components**

**1 . ALPRAZOLAM SANDOZ alprazolam 1 mg tablet blister pack**

**Dosage Form** Tablet

**Route of Administration** Oral

**Visual Identification** Alprazolam Sandoz 1 mg tablet is blue, biconvex, round, scored on one side.

**Active Ingredients**

alprazolam 1 mg

**Other Ingredients (Excipients)**

carmoisine aluminium lake

colloidal anhydrous silica

docusate sodium

indigo carmine aluminium lake

lactose monohydrate

magnesium stearate

microcrystalline cellulose

pregelatinised maize starch

sodium benzoate

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary