AUSTRALIAN PRODUCT INFORMATION

ALEPAM®

(oxazepam) tablet

1 NAME OF THE MEDICINE

Oxazepam

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ALEPAM 15 and ALEPAM 30 tablet contains 15 mg and 30 mg of oxazepam, respectively.

Excipients with known effect: sugars as lactose and trace quantities of sulfites.

For the full list of excipients, see Section 6.1 LIST OF EXCIPIENTS.

3 PHARMACEUTICAL FORM

ALEPAM 15 (oxazepam) 15 mg: 8 mm pale yellow flat bevelled edged tablet marked OM/15 on one side, G on reverse.

ALEPAM 30 (oxazepam) 30 mg: 8 mm pale orange flat bevelled edged tablet marked OM/30 on one side, G on reverse.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

ALEPAM is indicated for:

- Management of anxiety disorders or for the short-term relief of the symptoms of anxiety. Anxiety associated with depression is also responsive to oxazepam therapy. Anxiety or tension associated with the stress of everyday life usually does not require treatment with an anxiolytic. The physician should periodically reassess the usefulness of the drug for the individual patient.
- Alcoholics with acute tremulousness, confusional state or anxiety associated with alcohol withdrawal are responsive to therapy.

4.2 DOSE AND METHOD OF ADMINISTRATION

ALEPAM is administered orally. For optimal results, dose, frequency of administration and duration of therapy should be individualised according to patient response.

For mild to moderate anxiety, with associated tension, irritability, agitation or related symptoms of functional origin or secondary to organic disease, the usual dose is 7.5 to 15 mg, 3 or 4 times daily.

For severe anxiety syndromes, agitation or anxiety associated with depression, the usual dose is 15 to 30 mg, 3 or 4 times daily.

For older patients with anxiety, tension, irritability and agitation, the initial dose is 7.5 mg, 2 to 3 times daily. If necessary, increase cautiously to 15 mg, 3 or 4 times daily.

For alcoholics with tremulousness or anxiety on withdrawal, the usual dose is 15 to 30 mg, 3 or 4 times daily. ALEPAM should not be administered to alcoholics with acute inebriation.

Paediatric Use. ALEPAM is not indicated for use in children under 16 years of age.

The need for continued therapy with ALEPAM in patients who have been taking medication for several weeks should be evaluated periodically.

4.3 CONTRAINDICATIONS

ALEPAM is contraindicated in:

- Patients with known hypersensitivity to benzodiazepines.
- Patients with severe respiratory insufficiency, including chronic obstructive airways disease with incipient respiratory failure.
- Patients with severe pulmonary insufficiency.
- Patients with sleep apnoea.
- Patients with Myasthenia gravis.
- Patients with spinal or cerebellar ataxia.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Withdrawal

Following the prolonged use of ALEPAM at therapeutic doses, withdrawal from the medication should be gradual. An individualised withdrawal timetable needs to be planned for each patient in whom dependence is known or suspected. Periods tapering from four weeks to four months have been suggested. As with other benzodiazepines, including oxazepam, abrupt discontinuation may be associated with withdrawal reactions, when treatment is suddenly withdrawn, including mood changes, anxiety, restlessness or temporary increase of sleep disturbance can occur after use of ALEPAM.

After as little as one week of therapy withdrawal symptoms can appear following the cessation of recommended doses (e.g. rebound insomnia following cessation of a hypnotic benzodiazepine).

Abrupt discontinuation of oxazepam should be avoided and a gradual dosage-tapering schedule followed after extended therapy. As abrupt termination of treatment may be accompanied by withdrawal symptoms, treatment should be reduced gradually.

Withdrawal symptoms similar in character to those noted with barbiturates and alcohol have occurred following abrupt discontinuation of benzodiazepines. Withdrawal symptoms can appear following cessation of recommended doses after as little as one week of therapy. These symptoms can range from headache, restlessness, confusion, sweating, insomnia, anxiety, dysphoria, palpitations, panic attacks, vertigo, myoclonus, akinesia, myalgia, rebound phenomena, dysphoria, hyperacusis, numbness/tingling of extremities, involuntary movements, hyperreflexia, short-term memory loss, and hyperthermia, hypersensitivity to light, sound and touch, abnormal body sensations (e.g. feelings of motion, metallic taste), depersonalisation, derealisation, delusional beliefs, hyperreflexia and loss of short term memory. Major syndrome which may include convulsions or seizures, tremor, abdominal and muscle cramps, confusional states, delirium, hallucinations, hyperthermia, psychosis, vomiting and sweating.

Additional reported withdrawal symptoms include headache, tension, depression, irritability, dizziness, nausea, diarrhoea, loss of appetite, involuntary movements, perceptual disturbances, agitation, tachycardia.

Convulsions or seizures may be more common in patients with pre-existing seizure disorders or who are taking other drugs that lower the convulsive threshold such as antidepressants.

Such manifestations of withdrawal, especially the more serious ones, are more common in those patients who have received excessive doses over a prolonged period. However, withdrawal symptoms have also been reported following abrupt discontinuation of benzodiazepines taken continuously at therapeutic levels. Accordingly, ALEPAM should be terminated by tapering the dose to minimise occurrence of withdrawal symptoms. Patients should be advised to consult with their physician before either increasing the dose or abruptly discontinuing the medication.

Duration of treatment

In general, benzodiazepines should be prescribed for short periods only (e.g. 2 to 4 weeks), depending on the indication. Routine repeat prescription should be avoided. Continuous long-term use of ALEPAM is not recommended. Patients should be informed at initiation that treatment will be of limited duration and that the dose will be progressively reduced.

Amnesia

Transient amnesia or memory impairment has been reported in association with the use of benzodiazepines. Benzodiazepines may induce anterograde amnesia. The condition occurs most often several hours after ingesting the product and therefore to reduce the risk, patients should ensure that they will be able to have an uninterrupted sleep of 7-8 hours.

Narrow-angle glaucoma

Caution should be used in the treatment of patients with acute narrow-angle glaucoma (because of atropine-like side effects).

Blood Dyscrasias

In rare instances some patients taking benzodiazepines have developed blood dyscrasias, and some have had elevations of liver enzymes. As with other benzodiazepines, periodic blood counts and liver function tests are recommended.

Depression, Psychosis and Schizophrenia

ALEPAM is not recommended as primary therapy in patients with depression and psychosis. In such conditions, psychiatric assessment and supervision are necessary if benzodiazepines are indicated. Benzodiazepines may increase depression in some patients and may contribute to deterioration in severely disturbed schizophrenics with confusion and withdrawal. The use of benzodiazepines may unmask suicidal tendencies in depressed patients and should not be used without adequate antidepressant therapy.

Psychiatric and 'paradoxical reactions'

Treatment with benzodiazepines, including oxazepam, may cause psychiatric and paradoxical reactions, particularly in elderly patients and children.

Paradoxical reactions may include restlessness, agitation, irritability, aggressiveness, delusions, nightmares, hallucinations, psychosis, inappropriate behaviour, acute rage, stimulation or excitement, unmask of depressions with suicidal tendencies and other negative behavioral disorders. If such reactions occur, treatment of ALEPAM should be discontinued.

Impaired Respiratory Function

Caution in the use of ALEPAM is recommended in patients with respiratory depression. In patients with chronic obstructive pulmonary disease, benzodiazepines can cause increased arterial carbon dioxide tension and decreased arterial oxygen tension. Use of benzodiazepines, including ALEPAM, may lead to potentially fatal respiratory depression.

Epilepsy

Abrupt withdrawal of benzodiazepines in patients with convulsive disorders may be associated with a temporary increase in the frequency and/or severity of seizures.

Abuse

Caution must be exercised in administering ALEPAM to individuals known to be addiction prone or those whose history suggests they may increase the dosage on their own initiative. It is desirable to limit repeat prescription without adequate medical supervision.

Caution should particularly be exercised in patients with a history of alcohol or drug abuse, or in patients with severe personality disorder, as the risk of dependence and abuse potential is increased.

Dependence

The use of benzodiazepines may lead to the development of physical and psychical dependence, as defined by the presence of a withdrawal syndrome on discontinuation of the drug. The risk of dependency increases with the dose and duration of treatment, but dependency may also occur during short-term treatment within the therapeutic dose range.

Tolerance

Some loss of efficacy to the hypnotic effects of benzodiazepines may develop after repeated use for a few weeks. Tolerance to sedation may occur with benzodiazepines, especially in those with drug seeking behaviour. There is evidence that tolerance develops to the sedative effects of benzodiazepines.

Rebound Insomnia and Anxiety

Rebound phenomena have been described in the context of benzodiazepine use. Rebound insomnia and anxiety mean an increase in the severity of these symptoms beyond pre-treatment levels following cessation of benzodiazepines. Rebound phenomena in general possibly reflect re-emergence of pre-existing symptoms combined with withdrawal symptoms described earlier. Some patients prescribed benzodiazepines with very short half-lives (in the order of 2 to 4 hours) may experience relatively mild rebound symptoms in between their regular doses. Withdrawal/rebound symptoms may follow high doses taken for relatively short periods.

The risk of rebound phenomena is increased after abrupt discontinuation, it is recommended that the dosage is decreased gradually. Patients should be informed of the possibility of rebound phenomena to minimise anxiety should these occur during discontinuation.

Use in Hepatic Impairment

Patients with impaired hepatic function should use benzodiazepine medication with caution and dosage reduction may be advisable. In rare instances some patients taking benzodiazepines have developed blood dyscrasias, and some have had elevations of liver enzymes. As with other benzodiazepines, periodic blood counts and liver function tests are recommended.

As with all benzodiazepines, the use of ALEPAM may worsen hepatic encephalopathy; therefore, ALEPAM should be used with caution in patients with severe hepatic insufficiency and / or hepatic insufficiency.

Use in Renal Impairment

Patients with impaired renal function should use benzodiazepine medication with caution and dosage reduction may be advisable.

Use in the Elderly

Elderly or debilitated patients may be particularly susceptible to the sedative effects of benzodiazepines and associated giddiness, ataxia and confusion which may increase the possibility of a fall and consequently fractures in the elderly. Therefore, these patients should be monitored frequently and have their dosage adjusted carefully according to patient response.

Although hypotension has occurred only rarely, ALEPAM should be administered with caution to patients in whom a drop in blood pressure might lead to cardiac or cerebral complications. This is particularly important in elderly patients.

Paediatric Use

The safety and effectiveness of oxazepam has not been established in children less than 16 years of age. Benzodiazepines should not be given to children without careful assessment of the need to do so; the duration of treatment must be kept to a minimum.

Excipients

This medicinal product contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency, or galactose malabsorption should not take this medicine.

Effects on Laboratory Tests

Oxazepam may decrease values of leucocytes in testing for leucopoiesis.

Oxazepam may give high blood glucose level utilising the Somogyi procedure but not the glucose oxidase procedure.

Risk from concomitant use of opioids

Concomitant use of oxazepam and opioids may result in sedation, respiratory depression, coma and death. Because of these risks, concomitant prescribing of sedative medicines such as benzodiazepines or related drugs such as ALEPAM with opioids should be reserved for patients for whom alternative treatment options are not possible. If a decision is made to prescribe ALEPAM concomitantly with opioids, the lowest effective dose should be used, and the duration of treatment should be as short as possible.

The patients should be followed closely for signs and symptoms of respiratory depression and sedation. In this respect, it is strongly recommended to inform patients and their caregivers (where applicable) to be aware of these symptoms (see section 4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS).

Thyroid disease

In patients with hyperthyroidism an increased clearance and a shorter half-life of ALEPAM has been observed. Severe hypothyroidism may decrease the glucuronidation of ALEPAM.

Loss or bereavement

In cases of loss or bereavement, psychological adjustment may be inhibited by benzodiazepines.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

The benzodiazepines, including oxazepam, produce additive CNS depressant effects when co-administered with other medications which themselves produce CNS depression, e.g. barbiturates, alcohol, antipsychotics, sedatives/hypnotics, anxiolytics, tricyclic antidepressants, nonselective MAO inhibitors, phenothiazines and other antipsychotics, skeletal muscle relaxants, anticonvulsants, antihistamines or narcotic analgesics and anaesthetics.

The cytochrome P450 system has not been shown to be involved in the disposition of oxazepam and, unlike many benzodiazepines, pharmacokinetic interactions involving the P450 system have not been observed with oxazepam.

The anticholinergic effects of other drugs, including atropine and similar drugs, antihistamines and antidepressants may be potentiated.

The concomitant use of sedative medicines such as benzodiazepines or related drugs such as oxazepam, with opioids increases the risk of sedation, respiratory depression, coma and death because of additive CNS depressant effect. The dosage and duration of concomitant use should be limited (see section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE). Additionally, enhancement of the euphoria may also occur leading to an increase in psychic dependence. The elderly require special supervision.

Benzodiazepines in combination with 4-hydroxybutanoic acid (sodium oxybate) may cause an increased respiratory depression. Administration of theophylline or aminophylline may reduce the sedative effects of benzodiazepines, including oxazepam.

Interactions have been reported between some benzodiazepines and anticonvulsants, with changes in the serum concentration of the benzodiazepine or anticonvulsant. It is recommended that patients be observed for altered responses when benzodiazepines and anticonvulsants are prescribed together, and that serum level monitoring of the anticonvulsant be performed more frequently.

Minor EEG changes, usually low voltage fast activity, of no known clinical significance, have been reported with benzodiazepine administration.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on Fertility

Impairment of Fertility. Female mice fed diets containing 0.05% or 0.75% oxazepam were reported to exhibit significant decreases in the frequency of vaginal oestrus. Human data are not available.

Use in Pregnancy

Category C

Oxazepam should not be used during pregnancy. An increased risk of congenital malformations associated with the use of benzodiazepines during the first trimester of pregnancy has been suggested in several studies. In humans, umbilical cord blood samples indicate placental transfer of benzodiazepines including oxazepam and their glucuronide metabolites.

Infants of mothers who ingested benzodiazepines for several weeks or more preceding delivery have been reported to have withdrawal symptoms during the postnatal period. Symptoms such as hypoactivity, hypotonia, hypothermia, respiratory depression, apnoea, feeding problems, and impaired metabolic response to cold stress have been reported in neonates born of mothers who have received benzodiazepines during the late phase of pregnancy or at delivery.

Benzodiazepines cross the placenta and may cause hypotonia, reduced respiratory function and hypothermia in the newborn infant. Continuous treatment during pregnancy and administration of high doses in connection with delivery should be avoided. Withdrawal symptoms in newborn infants have been reported with this class of drugs.

The use of benzodiazepines during the first trimester of pregnancy should almost always be avoided. If the drug is prescribed to a woman of child-bearing potential, she should be warned to contact her physician regarding discontinuation of the drug if she intends to become or suspects that she is pregnant.

Non-Teratogenic Effects. The use of benzodiazepines during the last phase of pregnancy or at delivery may require ventilation of the infant at birth.

Use in Lactation

Caution should be exercised when ALEPAM is given to a breastfeeding woman. ALEPAM is excreted in human breast milk, and may cause drowsiness and feeding difficulties in the infant. ALEPAM should not be administered to breast-feeding women, unless the expected benefit to the woman outweighs the potential risk to the infant.

Sedation and inability to suckle have occurred in neonates of lactating mothers taking benzodiazepines. Infants of lactating mothers should be observed for pharmacological effects (including sedation and irritability).

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

As with all patients taking CNS-depressant medications, patients receiving ALEPAM should be warned not to operate dangerous machinery or motor vehicles until it is known that they do not become drowsy or dizzy from ALEPAM therapy. Abilities may be impaired on the day following use. Patients should be advised that their tolerance for alcohol and other CNS depressants will be reduced and that these medications should either be eliminated or given in reduced dosage in the presence of ALEPAM.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Within the system organ classes, adverse reactions are listed under headings of frequency (number of patients expected to experience the reaction), using the following categories: Very Common (≥ 1/10), Common (≥1/100 to <1/10), Uncommon (≥1/1,000 to <1/100), Rare (≥1/10,000 to <1/1,000), Very rare (<1/10,000), Not known (cannot be estimated from the available data).

Blood and lymphatic system disorders

Not known: Thrombocytopenia, agranulocytosis, pancytopenia.

Immune system disorders

Not known: Anaphylactic reaction, anaphylactoid reaction, hypersensitivity, skin reaction.

Metabolism and nutrition disorders

Not known: Inappropriate antidiuretic hormone secretion (SIADH), hyponatraemia.

Cardiovascular disorders

Less common: Oedema, hypotension.

Not known: blood pressure decreased.

Dermatological disorders

Less common: Skin rashes (morbilliform, urticarial and maculopapular).

Gastrointestinal disorders

Less common: Nausea, hepatic dysfunction, abdominal pain.

Not known: Constipation.

Haematological disorders

Less common: Leucopenia.

Musculo-Skeletal and connective tissue disorders

Common: Muscular weakness.

Less common: Tremor, paraesthesia.

Respiratory, thoracic and mediastinal disorders

The extent of respiratory depression with benzodiazepines is dose dependent, with more severe depression occurring with high doses.

Not known: Respiratory depression, apnoea, sleep apnoea syndrome exacerbated, obstructive pulmonary disease exacerbated.

Nervous System disorders

Benzodiazepine effects on the CNS are dose dependent, with more severe CNS depression occurring with high doses.

Very common: Sedation, somnolence. Mild drowsiness, if it occurs, is usually observed at the beginning of therapy and generally decreases in severity or disappears on continued medication or upon decreasing the dose.

Common: Ataxia, confusional state, dizziness

Less common:, vertigo, headache, syncope, ataxia, , hallucination, aggression, unpleasant dreams.

Not known: Coma, extrapyramidal disorder, convulsion, amnesia, tremor, vertigo, dysarthria

Psychiatric disorders and 'paradoxical reactions'

Common: Depression

Uncommon: Libido disorder, erectile dysfunction, orgasm abnormal,

Less common: Paradoxical reactions such as stimulation, excitement, or rage rarely occur (see Section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE).

Not known: Suicide attempt, suicidal ideation, hallucination, aggression, disinhibition, euphoric mood, agitation, hostility, disturbance in sexual arousal, anger, sleep disorder, insomnia, drug dependence.

Eye disorders

Not known: Visual impairment (including Diplopia and Vision blurred).

Hepatobiliary disorders

Not known: Jaundice, blood bilirubin increased, transaminases increased, blood alkaline phosphatase increased.

Skin and subcutaneous tissue disorders

Not known: Alopecia.

General disorders and administration site conditions

Very common: Fatigue.

Common: Asthenia.

Less common: Hypersensitivity, lethargy, altered libido, slurred speech, blurred vision, disorientation and fever.

Not known: Hypothermia, paradoxical drug reaction (anxiety).

Serious or Life-Threatening Reactions

Although rare, leucopenia and hepatic dysfunction including jaundice, have been reported during oxazepam therapy.

Reporting Suspected Adverse Effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

Symptoms

Overdosage of benzodiazepines is usually manifested by degrees of central nervous system depression ranging from drowsiness to coma. In mild cases, symptoms include drowsiness, mental confusion and lethargy. In more serious cases, symptoms may include ataxia, hypotonia, hypotension, respiratory depression, coma, and very rarely proves fatal.

Treatment

In the management of overdosage with any medication, it should be borne in mind that multiple agents may have been taken.

Following overdosage with oral benzodiazepines, vomiting should be induced (within one hour) if the patient is conscious, or gastric lavage undertaken with the airways protected if the patient is comatose. If there is no advantage in emptying the stomach, activated charcoal should be given to reduce absorption. Hypotension and respiratory depression should be managed according to general principles.

In mild cases patients should sleep under control of respiratory and circulatory function. In severe cases further measures (stabilization of circulatory function, intensive monitoring) may be required. Due to the high protein binding and the high volume of distribution of oxazepam forced diuresis or hemodialysis seem to be of small value. Flumazenil is indicated to antagonize the central depressive effect in case of intoxications with severe respiratory and cardiovascular impairment. Haemoperfusion and haemodialysis are not useful in benzodiazepine intoxication. The benzodiazepine antagonist flumazenil may be used in hospitalised patients for the reversal of acute benzodiazepine effects. The benzodiazepine antagonist flumazenil is not indicated in patients with epilepsy who have been treated with benzodiazepines. Antagonism of the benzodiazepine effect in such patients may trigger seizures. If excitation occurs, barbiturates should not be used. Please consult the flumazenil product information prior to usage.

For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of Action

Oxazepam is an anti-anxiety agent which belongs to the benzodiazepine class of drugs.

The exact mechanism of action of benzodiazepines has not yet been elucidated; however, benzodiazepines appear to work through several mechanisms. Benzodiazepines presumably exert their effects by binding to specific receptors at several sites within the central nervous system, either by potentiating the effects of synaptic or pre-synaptic inhibition mediated by gamma-aminobutyric acid or by directly affecting the action potential generating mechanisms.

Clinical Trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

Oxazepam is readily absorbed when given orally. Peak concentrations in plasma occur approximately 2 to 3 hours following administration of 30 mg. The half-life of oxazepam in human plasma ranges from 4 to 15 hours. At clinically relevant concentrations, oxazepam is 95% to 98% bound to plasma protein. Oxazepam is conjugated at its 3-hydroxy substituent to its glucuronide which accounts for at least 95% of the urinary excretion products. There are no active metabolites of oxazepam. Multiple-dose therapy leads to no excessive drug accumulation.

There is no indication of induction of drug-metabolising enzymes with oxazepam. Oxazepam is not a substrate for N-dealkylating enzymes of the cytochrome P450 system, nor is it hydroxylated to any significant extent.

The pharmacokinetics of oxazepam remain unaltered in older patients, however the elderly generally show increased central nervous system sensitivity to benzodiazepines, and may require a reduced dosage. Hepatic diseases (hepatitis, alcoholic cirrhosis) have a minimal influence on oxazepam kinetics, however these patients have increased cerebral sensitivity to benzodiazepines and dosage reduction may be advisable. As with other benzodiazepines, the pharmacokinetics of oxazepam may change in patients with impaired renal function and the medication should be used with caution.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

In-vitro mutagenicity reports on oxazepam are inconclusive. One study reported oxazepam to be mutagenic in a modified Ames Salmonella typhimurium test in the presence, but not in the absence, of metabolic activation. Other investigations (employing the Salmonella/microsome test, the Ames test, and tests in Aspergillus nidulans, Saccharomyces cerevisiae, isolated rat hepatocytes and a rat liver cell line) have obtained negative results for the mutagenicity of oxazepam.

Carcinogenicity

In a two-year carcinogenicity study in which rats were administered oxazepam in the diet (5, 15, 60 mg/kg/day), no oxazepam-related malignant tumours were found. However, there was a significant increase in the incidence of testicular interstitial cell tumours and thyroid cystadenomas (benign tumours) in high-dose males. There was also a significant trend for increased incidence of prostatic adenomas. An earlier published study reported that mice fed diets containing 0.05% or 0.15% oxazepam for nine months developed a dose-related increase in liver adenomas. In an independent analysis of some of the microscopic slides from this mouse study, several of these tumours were classified as liver carcinomas. Although comprehensive studies have not been performed to examine the possibility of an increased incidence of tumours in humans exposed to oxazepam, at the present time there is no evidence that the clinical use of oxazepam is associated with tumours.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

The tablets also contain the following inactive ingredients: lactose monohydrate, maize starch, quinoline yellow aluminium lake, erythrosine aluminium lake, magnesium stearate.

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 30°C.

6.5 NATURE AND CONTENTS OF CONTAINER

ALEPAM 15: HDPE bottles with PP child resistant closures and PVC/PVDC/Al blister packs of 25, 50, 90, 1000s

ALEPAM 30: PVC/PVDC/Al blister packs of 25, 50, 90, 1000s

Some strengths, pack sizes and/or pack types may not be marketed.

Australian Register of Therapeutic Goods (ARTG)

AUST R 17572 - ALEPAM 15 oxazepam 15 mg tablet bottle

AUST R 385081 - ALEPAM 15 oxazepam 15 mg tablet blister pack

AUST R 385082 - ALEPAM 30 oxazepam 30 mg tablet blister pack

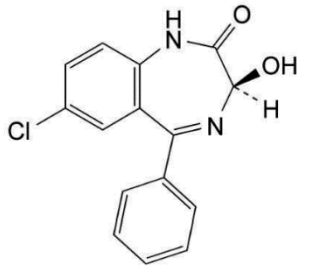
6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy.

6.7 PHYSICOCHEMICAL PROPERTIES

A white or almost white, crystalline powder, practically insoluble in water, slightly soluble in alcohol and in methylene chloride.

Chemical Structure



and enantiomer

Chemical name: (3*RS*)-7-chloro-3-hydroxy-5-phenyl-1,3-dihydro-2*H*-1,4-benzodiazepin-2-one

Molecular formula: $C_{15}H_{11}ClN_2O_2$

Molecular weight: 286.72

CAS Number

604-75-1

7 MEDICINE SCHEDULE (POISONS STANDARD)

S4 – Prescription Only Medicine

8 SPONSOR

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

9 DATE OF FIRST APPROVAL

20/09/1991

10 DATE OF REVISION

29/06/2026

Summary Table of Changes

Section Changed	Summary of New Information
All	Minor Editorial update
4.3- 5.0	Updated as per CCDS (dated 15th Jan 2026)

ALEPAM® is a Viatris company trade mark

ALEPAM_pi\ May26/00(CCDS 15- Jan- 2026)