Diazepam Injection (DBL)
MIMS Abbreviated Prescribing Information

Diazepam
Mayne Pharma
Section: 3(b) Antianxiety agents - Central Nervous System
Pregnancy Category: C*
Permitted in sport

Use: Anxiety states; agitation due to alcohol withdrawal; muscle spasm incl tetanus; spasticity in cerebral palsy, paraplegia, atheosisis, stiff man syndrome; status epilepticus; preop medication

Contraindications: CAL with incipient respiratory failure; sole therapy in depression, psychosis; IVI if vital signs depressed

Precautions: Prolonged use; abrupt withdrawal; alcohol, drug abuse history; impaired renal, hepatic, respiratory function; sleep apnoea; hypotension sensitive conditions; myasthenia gravis; acute narrow angle glaucoma; epilepsy; elderly, debilitated; depression; pregnancy, lactation, children, neonates

Adverse Reactions: CNS disturbances incl impaired alertness or memory, lowered seizure threshold, disorientation; muscle weakness, ataxia; hypotension; tolerance, dependence; blood dyscrasias (rare); hepatic dysfunction (rare); paradoxical reactions eg rage; inj. site reactions; others, see full PI

Interactions: CNS depressants incl. alcohol; disulfiram, cimetidine, ketoconazole, fluvoxamine, fluoxetine, omeprazole; anticonvulsants; anticholinergics; isoniazid; rifampicin; levodopa; thyroid function tests

Diazepam Injection (DBL) (Injection) Rx (S4) CMI
This product may cause drowsiness

Diazepam; ethanol, benzyl alcohol, benzoic acid, Na benzoate; amp
Pack 10 mg/2 mL [5] : PBS/RPBS or $90.94
Pack 10 mg/2 mL [50] : $48.08

Dose Give by IM or slow (5 mg/min) IVI. Adults: 2-10 mg IV or IMI every 3-4 hours as necessary; max 30 mg/8 hours. Cardioversion: 5-15 mg IVI, 5-10 mins before procedure. Endoscopic procedures: less than or equal to 20 mg (usually less than or equal to 10 mg) IVI immed. before or 5-10 mg IMI 30 mins before procedure. Anticonvulsant: 5-10 mg IVI, repeat every 10-15 mins to max 30 mg; repeat in 2-4 hours if necessary. Children: less than or equal to 0.25 mg/kg IVI over 3 mins; repeat after 15-30 mins if necessary. Status epilepticus. 1 month-5 years: 0.2-0.5 mg every 2-5 mins to max 5 mg; > 5 years: 1 mg every 2-5 mins up to max 10 mg, repeat in 2-4 hours if necessary. Tetanus: 1 month-5 years: 1-2 mg IM or slow IVI; > 5 years: 5-10 mg; repeat every 3-4 hours as necessary

MIMS Full Prescribing Information

MIMS revision date: 1/11/00
Composition Active. Diazepam.

Inactive. Propylene glycol 45% v/v, ethanol absolute 10% v/v, benzyl alcohol 1.5% v/v, sodium benzoate 9.8% w/v, benzoic acid 0.24% w/v, water for injections.

Description Chemical name: 7-chloro-1,3-dihydro-1-methyl-5-phenyl-2H-1,4-benzodiazepin-2-one.
MW: 284.74. CAS: 439-14-5. It is a colourless crystalline compound, insoluble in water. pH 6.2 to 6.9.

Actions Benzodiazepine.

Pharmacology. Diazepam is a member of the group of classical benzodiazepines and exhibits anxiolytic, sedative, muscle relaxant and anticonvulsant effects. This is presumed to be the result of facilitating the action in the brain of gamma-aminobutyric acid (GABA), a naturally occurring inhibitory neurotransmitter. The effects of diazepam may result from action in the limbic and subcortical levels of the central nervous system (CNS). Benzodiazepines are capable of producing all levels of CNS depression (i.e. mild sedation to hypnosis to coma).

Pharmacokinetics. Diazepam may be given by intravenous (IV) or intramuscular (IM) injection but absorption following intramuscular administration may be slow and erratic, depending on the muscle mass used and other factors. When diazepam is injected into the deltoid muscle, absorption is usually rapid and complete.

Plasma concentrations of diazepam and its active metabolites exhibit considerable interpatient variation, and therapeutic plasma concentrations are difficult to define. The plasma concentration time curve is biphasic, an initial rapid and extensive distribution phase with a half-life of up to three hours, followed by a prolonged terminal elimination phase (half-life 20 to 48 hours). The elimination half-life is 90 hours at age 80 and increased two to threefold in patients with cirrhosis.
The drug is metabolised in the liver to hydroxydiazepam (temazepam) and nordiazepam (t1/2 approximately 96 hours) and ultimately to oxazepam. Diazepam is excreted mainly (about 70%) in the urine in free form or predominantly as glucuronide and sulfate metabolites. Diazepam is 98% protein bound in the plasma. Diazepam and its metabolites readily diffuse across the blood-brain barrier and placenta. They also appear in the milk of breastfeeding mothers.

During repeated dosing of diazepam, accumulation of diazepam and its active metabolites may occur. Accumulation continues until a steady state plasma concentration is reached, which usually takes five days to two weeks after initiation of therapy. The elimination of diazepam after reaching steady state levels is slow since active metabolites may remain in the blood for several days or even weeks, possibly resulting in persistent effects.

The elimination half-life may be prolonged in the newborn infant, the elderly and patients with hepatic or renal disease and it should be noted that the plasma concentration may take correspondingly longer to reach steady state.

Indications Management of anxiety disorders or for the short-term relief of symptoms of anxiety. Anxiety or tension associated with the stress of everyday life usually does not require treatment with an anxiolytic. In acute alcohol withdrawal, diazepam may be useful in the symptomatic relief of acute agitation, tremor, impending or acute delirium tremens and hallucinosis.

Diazepam is a useful adjunct for the relief of reflex muscle spasms due to local trauma (injury, inflammation) to muscles, bones and joints. It can also be used to combat spasticity due to upper motor neuron lesions such as cerebral palsy and paraplegia, as well as in athetosis and stiff man syndrome. Intravenous diazepam is useful in controlling status epilepticus and the spasms of tetanus. Diazepam is also used as preoperative medication.

Contraindications Known hypersensitivity to benzodiazepines.

Chronic obstructive airways disease with incipient respiratory failure.

As sole therapy in psychosis including primary depressive disorders.

Benzodiazepines are not recommended for the primary treatment of psychotic illness.

Benzodiazepines should not be used alone to treat depression or anxiety associated with depression as suicide may occur in such patients.

The drug should not be administered intravenously to patients in shock, coma, patients with cardiac or respiratory insufficiency or those with acute alcoholic intoxication with depressed vital signs.

Precautions Following the prolonged use of diazepam 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 from four weeks to four months have been suggested. As with other benzodiazepines when diazepam treatment is suddenly withdrawn, a temporary increase in sleep disturbance can occur (see Dependence, below).

In general, benzodiazepines should be prescribed for short periods only (e.g. 2 to 4 weeks). Continuous long-term use of diazepam is not recommended. There is evidence that tolerance develops to the sedative effect of benzodiazepines. 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).

Circulatory consequences. Although hypotension has occurred only rarely, parenteral diazepam 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.

Memory impairment. Transient amnesia or memory impairment has been reported in association with the use of benzodiazepines. Anterograde amnesia may occur using therapeutic doses, the risk increasing at higher doses. Amnestic effects may be associated with inappropriate behaviour.

Disorientation. Patients should be warned as to the possibility of prolonged disorientation due to the long
half-life of diazepam. This may especially be true where diazepam is used for premedication. Myasthenia gravis. Diazepam Injection could increase the muscle weakness in myasthenia gravis and should be used with caution in this condition.

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

Impaired renal/liver function and blood dyscrasias. Patients with impaired renal or 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 and kidney function tests are recommended.

Depression, psychosis and schizophrenia. Diazepam Injection is not recommended as primary therapy in patients with depression or 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. Suicidal tendencies may be present or uncovered and protective measures may be required.

Paradoxical reactions. Paradoxical reactions such as restlessness, agitation, irritability, aggressiveness, delusion, nightmares, hallucinations, psychoses, inappropriate behaviour and other adverse behavioural effects, acute rage, stimulation or excitement may occur; should such reactions occur, diazepam injection should be discontinued. They are more likely to occur in children and the elderly.

Elderly or debilitated patients. Such 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. Extreme care must be used in administering injectable diazepam, particularly by the intravenous route, to the elderly, to very ill patients and to those with limited pulmonary reserve because of the possibility that apnoea and/or cardiac arrest may occur. Concomitant use of barbiturates, alcohol, or other CNS depressants increases depression, with increased risks of apnoea. Lower doses should be used for elderly and debilitated patients.

Impaired respiratory function. Caution in the use of parenteral diazepam is recommended in patients with respiratory depression. In patients with chronic obstructive pulmonary disease, benzodiazepines can cause increased arterial carbon dioxide tension and decreased oxygen tension. A lower dose is recommended for patients with chronic respiratory insufficiency, due to the risk of respiratory depression. Diazepam should be used with caution in patients with sleep apnoea.

Epilepsy. When parenteral diazepam is administered to persons with convulsive disorders an increase in the frequency and/or severity of grand mal seizures may occur, necessitating increased anticonvulsant medication. Abrupt withdrawal of benzodiazepines in persons with convulsive disorders may be associated with a temporary increase in the frequency and/or severity of seizures.

Abuse. Extreme caution must be exercised in administering diazepam to individuals with a history of alcohol or drug abuse or those known to be addiction prone or those whose history suggests they may increase the dosage on their own initiative.

Dependence. The use of benzodiazepines may lead to dependence as defined by the presence of a withdrawal syndrome on discontinuation of the drug. The risk of dependence increases with dose and duration of treatment. It is more pronounced in patients on long-term therapy and/or high dosage and particularly so in predisposed patients with a history of alcohol or drug abuse. Tolerance as defined by a need to increase the dose in order to achieve the same therapeutic effect seldom occurs in patients receiving recommended doses under medical supervision. Tolerance to sedation may occur with benzodiazepines, especially in those patients with drug seeking behaviour.

Withdrawal symptoms similar in character to those noted with barbiturates and alcohol have occurred once physical dependence to benzodiazepines has developed or following abrupt discontinuation of benzodiazepines. These symptoms can range from insomnia, anxiety, dysphoria, palpitations, panic attacks, vertigo, myoclonus, akinesia, 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 to a major syndrome which may include convulsions, tremor, abdominal and muscle cramps, confusional state, delirium, hallucinations, hyperthermia, psychosis,
vomiting and sweating. Such manifestations of withdrawal, especially the more serious ones, are more
common in patients who have received excessive doses over an extended period of time. However,
withdrawal symptoms have been reported following abrupt discontinuation of benzodiazepines
administered continuously at therapeutic levels. Accordingly, diazepam injection should be terminated by
tapering the dose to minimise occurrence of withdrawal symptoms.

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 pretreatment levels following
cessation of benzodiazepines. Rebound phenomena in general, possibly reflect re-emergence of pre-
existing symptoms combined with withdrawal symptoms described earlier. Withdrawal/ rebound
symptoms may follow high doses for relatively short periods.

Injection technique. When used intravenously, the following procedures should be adopted to reduce the
possibility of venous thrombosis, phlebitis, local irritation, swelling and rarely, vascular impairment. The
solution should be injected slowly, taking at least one minute for each 5 mg (1 mL) given, into a large
lumen vessel, such as an antecubital vein. Do not use small veins such as those on the dorsum of the
hand or wrist. Extreme care should be taken to avoid intra-arterial administration or extravasation.
Impaired renal function. See Precautions, Impaired renal/ liver function and blood dyscrasias.
Impaired hepatic function. See Precautions, Impaired renal/ liver function and blood dyscrasias.
Use in the elderly. See Precautions, Elderly or debilitated patients.

Use in pregnancy. (Category C)

The safety of diazepam for use in human pregnancy has not been established. An increased risk of
congenital malformation associated with the use of benzodiazepines during the first trimester of
pregnancy has been suggested. Benzodiazepines should be avoided during pregnancy unless there is no
safer alternative.

Benzodiazepines cross the placenta and may cause hypotension, hypotonia, respiratory depression and
hyperthermia 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 drug. Special care must be taken when diazepam is used during labour and
delivery, as single high doses may produce irregularities in the fetal heart rate and hypotonia, poor
suckling, hyperthermia and moderate respiratory depression in the neonate. With newborn infants, it must
be remembered that the enzyme system involved in the breakdown of the drug is not yet fully developed
(especially in premature infants).

Use in lactation. Diazepam is excreted in human breast milk, and may cause drowsiness and feeding
difficulties in the infant. Since diazepam passes into breast milk, injectable diazepam should not be
administered to breastfeeding mothers.

Use in children. Efficacy and safety of parenteral diazepam have not been established in the neonate (30
days or less in age). Prolonged CNS depression has been observed in neonates due to inability to
transform the drug. The benzyl alcohol contained in Diazepam Injection ampoules may lead to irreversible
damage in the newborn, especially in the premature infant. A fatal toxic syndrome consisting of metabolic
acidosis, CNS depression, respiratory problems, renal failure, hypotension and possibly seizures and
intracranial haemorrhages has been associated with this use. Therefore, for these patients the ampoules
should only be used if no therapeutic alternative is available.

Effect on ability to drive or operate machinery. Sedation, amnesia, impaired concentration and impaired
muscle function may adversely affect the ability to drive or operate machinery. As with all patients taking
CNS depressant medications, patients receiving diazepam should be warned not to operate dangerous
machinery or drive motor vehicles until it is known that they do not become drowsy or dizzy from
diazepam 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 diminished and that these medications should either be
eliminated or given in reduced dosage in the presence of diazepam.

Interactions The benzodiazepines, including diazepam, produce additive CNS depressant effects when
coadministered with other medications which themselves produce CNS depression, e.g. barbiturates,
alcohol, anxiolytics, sedatives, antidepressants including tricyclic antidepressants, nonselective
monoamine oxidase inhibitors (MAOIs), hypnotics, antiepileptic drugs, phenothiazines and other antipsychotics, skeletal muscle relaxants, antihistamines, narcotic analgesics and anaesthetics (see Precautions). Therefore, it should be borne in mind that the effect of these drugs may potentiate or be potentiated by the action of Diazepam Injection.

Concomitant use with alcohol is not recommended due to enhancement of the sedative effect. There is a potentially relevant interaction between diazepam and compounds which inhibit certain hepatic enzymes (particularly cytochrome P450 3A). Data indicate that these compounds influence the pharmacokinetics of diazepam and may lead to increased and prolonged sedation.

Diazepam undergoes oxidative metabolism, and consequently may interact with disulfiram, cimetidine, ketoconazole, fluvoxamine, fluoxetine or omeprazole resulting in increased plasma levels of diazepam. Patients should be observed closely for evidence of enhanced benzodiazepine response during concomitant treatment with these drugs; some patients may require a reduction in benzodiazepine dosages.

There have also been reports that the metabolic elimination of phenytoin is affected by diazepam. The anticholinergic effects of other drugs including atropine and similar drugs, antihistamines and antidepressants may be potentiated.

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.

Isoniazid may increase plasma diazepam levels.

Rifampicin may enhance the elimination of diazepam, leading to decreased plasma diazepam levels. Diazepam may decrease the control of parkinsonian symptoms in patients taking levodopa. Diazepam should therefore be administered with caution to patients who are taking levodopa.

Laboratory tests. Diazepam can inhibit binding of thyroxine and liothyronine to their binding proteins resulting in erroneously abnormal values from thyroid function tests.

Adverse Reactions More common reactions. The most commonly reported undesirable effects are fatigue, drowsiness, muscle weakness, dizziness and ataxia; they are usually dose related. Less common reactions. The following effects are encountered infrequently.

Haematological. Blood dyscrasias including neutropenia, agranulocytosis, anaemia, leucopenia, thrombocytopenia.

Intramuscular injection (but not intravenous injection) may lead to a rise in serum creatinine phosphokinase activity, a maximum occurring 12 to 24 hours after injection. This fact should be taken into account in the differential diagnosis of myocardial infarction.

Cardiovascular. Hypotension, bradycardia and cardiac arrest, tachycardia, palpitations. Ventricular premature contractions and other arrhythmias.

The propylene glycol in Diazepam Injection may lead to cardiovascular depression.

Ophthalmological. Conjunctivitis, nystagmus, blurred vision, diplopia.

Respiratory system. Decreased gag reflex. Coughing, dyspnoea, respiratory depression, hyperventilation, laryngospasm and pain in the throat or chest.

The propylene glycol in Diazepam Injection may lead to respiratory depression.

Genitourinary. Urinary retention, difficulty in micturition, incontinence.

Gastrointestinal. Nausea and vomiting, diarrhoea, constipation, gastrointestinal disturbance, dryness of mouth or hypersalivation.

Hepatobiliary. Elevated transaminases and alkaline phosphatase, hepatic dysfunction, jaundice.
Neurological (CNS). Vertigo, amnesia, confusion, mental depression, headache, slurred speech, numbed emotion, reduced alertness, lightheadedness, syncope.

Anterograde amnesia may occur using therapeutic dosages, the risk increasing at higher doses. Amnestic effects may be associated with inappropriate behaviour.

Paradoxical reactions such as anxiety, acute hyperexcitation, panic, aggression, auditory and visual hallucinations, increased muscle spasticity, insomnia, rage, sleep disturbances and stimulation have been reported; should these occur, use of diazepam should be discontinued.

Emergence or worsening of mental depression, including suicidal ideation, also has been associated with benzodiazepine use, principally in patients with pre-existing depression.

Diazepam may produce increased incidence and severity of seizures, especially on withdrawal of diazepam in patients with epilepsy or a history of seizures. Minor EEG changes, usually low voltage fast activity, of no known clinical significance, have been reported with benzodiazepine administration.

Hypersensitivity and dermatological. Rash, urticaria, pruritus, photosensitivity, immediate hypersensitivity reactions.

Body as a whole. Increase or decrease in libido, tremor, body and joint pains, muscle cramps, muscular weakness, hyperpyrexia, hypothermia.

Injection site reactions. Injection site reactions such as venous thrombosis, phlebitis, pain, local irritation and swelling or less frequently, vascular changes, may occur (particularly after rapid intravenous injection). Intramuscular administration can result in local pain, in some cases accompanied by erythema, at the site of injection. Tenderness is relatively common.

Dosage and Administration Diazepam may be administered intravenously or intramuscularly (deep into the muscle). However, absorption following intramuscular administration is slow and erratic; thus this route of administration should be avoided if possible. Too rapid injection or the use of veins with too small a lumen carries the risk of syncpe, apnoea, hypotension, bradycardia or cardiac or respiratory arrest and thrombophlebitis. Resuscitation equipment must be kept ready at all times. Intra-arterial injection must be carefully avoided on account of the danger of necrosis, and extravasation must be strictly avoided because venous thrombosis, phlebitis, local irritation, swelling or, less frequently, vascular changes may occur, particularly after rapid intravenous injection.

Lower doses should be used in the elderly, those with impaired hepatic or renal function or debilitated patients. These patients should be checked regularly at the start of treatment in order to minimise the dosage and/or frequency of administration to prevent overdose due to accumulation.

Adults. The usual adult dose is 2 to 10 mg by intramuscular or intravenous injection repeated every three to four hours as required. In general, the maximum adult dose should not exceed 30 mg over an eight hour period.

Intravenous injections should be given into a large vessel, such as an antecubital vein, and the solution should be administered slowly at a rate not exceeding 5 mg/minute (see Precautions.)

Cardioversion. To provide light anaesthesia and anterograde amnesia prior to cardioversion, diazepam 5 to 15 mg may be given by intravenous injection within five to ten minutes before the procedure.

Endoscopic procedures. To reduce anxiety, diazepam may be administered by slow intravenous injection immediately before the procedure; dosage should be titrated to obtain the desired sedative response. Generally, a dosage of up to 10 mg is adequate, but up to 20 mg intravenously may be given, particularly if opiates are not given concomitantly. If the intravenous route is not feasible, 5 to 10 mg may be given intramuscularly approximately 30 minutes before the procedure.

Anticonvulsant. In the convulsing patient, it is preferred that diazepam be given intravenously. However, intramuscular injection may be used if intravenous administration is impossible. Initially, 5 to 10 mg may be given, repeated if necessary at 10 to 15 minute intervals up to a maximum dose of 30 mg. If necessary, a further dose may be repeated in two to four hours, however, residual active metabolites may persist and readministration should be made with this consideration.

Children. Benzodiazepines should not be given to children without careful assessment of the indication;
the duration of treatment must be kept to a minimum. Intravenous administration should be made slowly over a three minute period at a dosage not exceeding 0.25 mg/kg. After an interval of 15 to 30 minutes, the initial dose may be repeated.

Caution. Diazepam injection contains benzyl alcohol. Medications containing benzyl alcohol are not recommended for use in neonates (see Precautions, Use in Children).

Status epilepticus and severe recurrent convulsive seizures. Slow intravenous administration is preferred. Infants over 30 days of age and children under 5 years: 0.2 to 0.5 mg slowly every two to five minutes up to a maximum of 5 mg.

Children 5 years or older: 1 mg every two to five minutes up to a maximum of 10 mg. Repeat in two to four hours if necessary. EEG monitoring of the seizure may be helpful.

Tetanus. Infants over 30 days of age and children under 5 years: 1 to 2 mg intramuscularly or by slow intravenous injection, repeated every three to four hours as necessary.

Children 5 years and older: 5 to 10 mg repeated every three to four hours as necessary.

Compatibility. In general, the administration of diazepam by dilution or mixture with intravenous fluids or other drugs should be avoided. Diazepam may precipitate out of intravenous solutions and adsorbs to the plastic of intravenous bags and tubing. Where the administration of diazepam by intravenous infusion is indicated, glucose intravenous infusion 5% or sodium chloride intravenous infusion 0.9% of minimum volume 250 mL should be used. The amount of diazepam added should not exceed 20 mg. The required dose of diazepam should be quickly and thoroughly mixed with the total volume of the infusion medium and the infusion begun immediately. The possibility of overloading the patient with fluid should be kept in mind.

Overdosage. 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 death.

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

Treatment is purely supportive of respiratory and cardiovascular function, and special attention should be paid to these functions in intensive care. Maintenance of adequate pulmonary ventilation is essential. The use of pressor agents intravenously may be necessary to combat hypotension. Fluids should be administered intravenously to encourage diuresis. 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. Please consult the flumazenil product information (Section 20a) prior to usage. The use of flumazenil is not recommended in epileptic patients who have been treated with Diazepam (or any other benzodiazepine). The reversal of the benzodiazepine effect could induce convulsions in such patients.

Presentation Ampoules, 10 mg/2 mL: 5's, 50's.
Storage Store below 25 deg. C. Protect from light.
Poison Schedule S4.
Date of TGA approval or last amendment 28/06/2000