NEW ZEALAND DATA SHEET

1 PRODUCT NAME

Lorazepam-AFT 4 mg/mL solution for injection

Lorazepam-AFT 2 mg/mL solution for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Lorazepam-AFT 4 mg/mL solution for injection contains 4 mg lorazepam per 1 mL ampoule.

Lorazepam-AFT 2 mg/mL solution for injection contains 2 mg lorazepam per 1 mL ampoule.

Excipients with known effects:

Lorazepam-AFT 4 mg/mL solution for injection: Propylene glycol (843 mg/ampoule)

Lorazepam-AFT 2 mg/mL solution for injection: Propylene glycol (845 mg/ampoule)

For the full list of excipients, see 6.1 List of excipients

3 PHARMACEUTICAL FORM

Lorazepam-AFT solution for injection is a clear, colourless sterile solution contained in a glass ampoule.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

- Pre-operative medication.
- Premedication for prolonged investigations.
- The treatment of acute anxiety states, acute agitation.
- The control of status epilepticus in adults, adolescents and children. (See Section 4.2 Dose and Method of Administration)

4.2 DOSE AND METHOD OF ADMINISTRATION

Use in one patient on one occasion only and discard any residue.

Dosage and duration of therapy should be individualised. The lowest effective dose should be prescribed for the shortest time possible. Prolonged repeat injections or infusions are not appropriate because of the possibility of propylene glycol toxicity.

Lorazepam injection is not recommended for outpatient use.

It is recommended that patients receiving lorazepam injection should remain under observation for at least eight hours and preferably overnight.

Method of administration

Lorazepam injection can be given intravenously or intramuscularly. However, the intravenous route is to be preferred. Care should be taken to avoid injection into small veins and intra-arterial injection.

Absorption from the injection site is considerably slower if the intramuscular route is used.

Lorazepam injection should not be used for long-term chronic treatment.

Preparation of injection

Intramuscular injection

A 1:1 dilution of lorazepam injection with normal saline or sterile water for injection is recommended in order to facilitate intramuscular administration.

Intravenous administration

For intravenous administration, lorazepam injection should always be diluted with normal saline or sterile water for injection as a 1:1 dilution.

Lorazepam injection is presented as a 1 mL solution in a 2 mL ampoule to facilitate dilution. Lorazepam injection should not be mixed with other drugs in the same syringe.

Lorazepam-AFT diluted 1:1 with normal saline or sterile water for injection is chemically and physically stable for 24 hours at 25 °C or 2 °C to 8 °C. However, to reduce microbial hazard, the injection should be administered immediately after preparation.

Do not use if solution has developed a colour or a precipitate.

Dosage

Pre-operative medication

Children and adolescents: Use of lorazepam injection for this indication is not recommended in children or adolescents.

Adults: 0.05 mg/kg (3.5 mg for an average 70 kg man). By the intravenous route the injection should be given 30-45 minutes before surgery. After IV administration, some sedation will be evident after 5-10 minutes and maximal loss of recall will occur after 30-45 minutes. By the intramuscular route the injection should be given 1-1.5 hours before surgery; some sedation will be evident 30-45 minutes after IM dosing and maximal loss of recall will occur after 60-90 minutes.

The maximum daily dose is 0.05 mg/kg (or 3.5 mg for an average 70 kg man).

Premedication for prolonged investigations

Children and adolescents: Use of lorazepam injection for this indication is not recommended in children or adolescents.

Adults: Dosage should be as for pre-operative medication: 0.05 mg/kg (3.5 mg for an average 70 kg man). By the intravenous route the injection should be given 30 - 45 minutes before the investigation. Lorazepam injection is not recommended for outpatient

use. It is recommended that patients receiving lorazepam injection should remain under observation for at least eight hours and preferably overnight.

Acute Anxiety

Children and adolescents: Use of lorazepam injection for this indication is not recommended in such patients.

Adults: Patients should be treated with an initial 1-2 mg IM or IV dose, which can be repeated as necessary up to 4 times daily with a maximum daily dose of 6 mg.

Elderly patients (65 years or over): Patients should be treated with an initial 0.5-1 mg IM or IV dose, which can be repeated as necessary up to a maximum dose of 4 mg.

Acute Agitation

Children and adolescents: Use of lorazepam injection for this indication is not recommended in such patients.

Adults: Patients should be treated with an initial 1-2 mg IM or IV dose, which can be repeated as necessary up to 4 times daily with a maximum daily dose of 6 mg.

Elderly patients (65 years or over): Patients should be treated with an initial 0.5-1mg IM or IV dose, which can be repeated as necessary up to a maximum dose of 4 mg.

Status Epilepticus

Infants and Neonates: Use of lorazepam injection for this indication is not recommended in infants and neonates.

Children < 6 years: Administer 0.05-0.1 mg/kg of the diluted injection intravenously as a slow bolus injection over 1-2 minutes. The dose may be repeated after 5-10 minutes if seizures continue.

Adolescents & Children ≥ 6 years: Administer 0.05-0.1 mg/kg (maximum 2 mg) of the diluted injection intravenously as a slow bolus injection over 1-2 minutes. The dose may be repeated after 5-10 minutes if seizures continue. Maximum dose: 4 mg.

Adults: Administer a 4 mg dose of the diluted injection intravenously as a slow bolus injection over 1-2 minutes. The dose may be repeated after 5-10 minutes if seizures continue. Maximum dose: 8 mg.

Patients with Renal or Hepatic impairment

Lower doses may be sufficient in these patients (See section 4.4 Special warnings and precautions for use).

Elderly and debilitated patients

For elderly and debilitated patients reduce the initial dose by approximately 50% and adjust the dosage as needed and tolerated (see section 4.4 Special warnings and precautions for use).

4.3 CONTRAINDICATIONS

- Pulmonary insufficiency

- Hypersensitivity to benzodiazepines, including lorazepam or to any of the excipients listed in Section 6.1
- Sleep apnoea syndrome
- Myasthenia gravis
- Severe hepatic insufficiency

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Severe anaphylactic/anaphylactoid reactions

Severe anaphylactic/anaphylactoid reactions have been reported with the use of benzodiazepines. Cases of angioedema involving the tongue, glottis or larynx have been reported in patients after taking the first or subsequent doses of benzodiazepines. Some patients taking benzodiazepines have had additional symptoms such as dyspnoea, throat closing, or nausea and vomiting. Some patients have required medical therapy in the emergency department. If angioedema involves the tongue, glottis or larynx, airway obstruction may occur and be fatal. Patients who develop angioedema after treatment with a benzodiazepine should not be rechallenged with the drug.

Impaired Respiratory Function

Caution in the use of lorazepam 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.

Amnesia

Transient amnesia or memory impairment has been reported in association with the use of lorazepam.

Dependence and Abuse

There are no clinical data available for lorazepam injection with regard to abuse or dependence. Continuous long-term use of lorazepam is not recommended.

Depression, Psychosis and Schizophrenia

Lorazepam 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. Suicidal tendencies may be present or uncovered and protective measures may be required. Therefore, benzodiazepines should be used with caution in patients with signs and symptoms of a depressive disorder or suicidal tendencies.

CNS and/or Paradoxical reactions

As with other benzodiazepines and CNS active drugs, three idiosyncratic symptom clusters, which may overlap, have been described.

- Amnestic symptoms: anterograde amnesia with appropriate or inappropriate behaviour;

- Confusional states: disorientation, derealisation, depersonalization and/or clouding of consciousness; and
- Agitational states: sleep disturbances, restlessness, irritability, aggression and excitation.

Lorazepam should be discontinued if confusion or agitation occurs.

Paradoxical reactions such as acute rage, stimulation or excitement may occur. Should such reactions occur, lorazepam should be discontinued.

Hypotension

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

There is no evidence to support the use of lorazepam injection in coma or shock.

Glaucoma

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

Myasthenia gravis

Lorazepam could increase the muscle weakness in myasthenia gravis and should be used with caution in this condition.

Concomitant use with alcohol/CNS depressants including opiates

The concomitant use of lorazepam with alcohol or/and CNS depressants should be avoided. Such concomitant use has the potential to increase the clinical effects of lorazepam which may include severe sedation, clinically relevant respiratory and/or cardio-vascular depression (see Section 4.5 Interactions with Other Medicines and Other Forms of Interactions).

Concomitant use of benzodiazepines and opioids may result in sedation, respiratory depression, coma, and death.

Propylene glycol

This medicine contains propylene glycol.

Co-administration with any substrate for alcohol dehydrogenase such as ethanol may induce serious adverse effects in neonates and children less than 5 years old.

Medical monitoring is required in paediatric patients with impaired renal or hepatic functions who receive ≥ 50 mg/kg/day of propylene glycol because various adverse events attributed to propylene glycol have been reported such as renal dysfunction (acute tubular necrosis), acute renal failure and liver dysfunction.

Use in hepatic and renal impairment

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

As with all benzodiazepines, the use of lorazepam may worsen hepatic encephalopathy.

Patients with hepatic or renal impairment may be prone to propylene glycol accumulation and toxicity.

Blood Dyscrasias

Use benzodiazepine medication with caution and dosage reduction may be advisable.

Use in the 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.

Lower doses should be used in elderly patients (see Section 4.2 Dose and Method of Administration).

Paradoxical reactions may be more likely to occur in the elderly (see section 4.4 Special warnings and precautions for use).

Monitoring

Some patients taking benzodiazepines have developed a blood dyscrasia, and some have had elevations in liver enzymes. Periodic haematologic and liver-function assessments are recommended where repeated courses of treatment are considered clinically necessary.

Paediatric use

Paradoxical reactions may be more likely to occur in children (see section 4.4 Special warnings and precautions for use).

Lorazepam is not recommended for use in the treatment of anxiety, agitation or as a pre-surgical medication in children.

Lorazepam injection contains propylene glycol. Paediatric patients may be prone to propylene glycol accumulation and toxicity. The recommended maximum daily dose is 50 mg/kg in children ≥ 5 years. See also above in section 4.4 Special warnings and precautions for use.

Paediatric Neurotoxicity

Some published studies in children have observed cognitive deficits after repeated or prolonged exposures to anaesthetic agents early in life. These studies have substantial limitations, and it is not clear if the observed effects are due to the anaesthetic/analgesic/sedation drug administration or other factors such as the surgery or underlying illness.

Published animal studies of some anaesthetic/analgesic/sedation drugs have reported adverse effects on brain development in early life and late pregnancy. The clinical significance of these nonclinical finding is yet to be determined.

Depending on the drug and patient characteristics, as well as dosage, the elimination phase may be prolonged relative to the period of administration resulting in longer exposure to the drug.

Effects on laboratory tests

No interference with laboratory tests has been identified or reported with the use of lorazepam.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Pharmacodynamic interactions

Sedation

Not recommended: Concomitant intake with alcohol.

The sedative effects may be enhanced when the product is used in combination with alcohol.

Patients should be advised that their tolerance for alcohol and other CNS depressants will be diminished in the presence of lorazepam injection. Alcoholic beverages should not be consumed for at least 24 to 48 hours after receiving lorazepam injection.

The benzodiazepines, including lorazepam injection, produce additive CNS depressant effects including respiratory depression, when co-administered with other medications which themselves produce CNS depression, e.g. opioids, and narcotic analgesics, barbiturates, sedatives/hypnotics, anxiolytics, antidepressants, non-selective MAO inhibitors, phenothiazines and other antipsychotics, sedative antihistamines, scopolamine and anaesthetics.

The addition of scopolamine to lorazepam injection is not recommended, since their combination has been observed to cause an increased incidence of sedation, hallucination and irrational behaviour.

Concomitant use of clozapine and lorazepam may produce marked sedation, excessive salivation, and ataxia.

There have been reports of apnoea, coma, bradycardia, heart arrest and death with the concomitant use of lorazepam injection solution and haloperidol.

Opioids

The concomitant use of sedative medicines such as benzodiazepines or related drugs such as lorazepam 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).

Administration of theophylline or aminophylline may reduce the sedative effects of benzodiazepines, including lorazepam.

Skeletal Muscle Relaxants

The action of skeletal muscle relaxants may be enhanced.

Anticholinergic effects

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

Pharmacokinetic interactions

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

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.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

A pre-implantation study in rats was performed with oral lorazepam at a 20 mg/kg dose which showed no impairment of fertility.

Use in pregnancy

Category C

Lorazepam is not recommended for use in pregnant women. Benzodiazepines may cause foetal damage when administered during first trimester. The use of lorazepam during the first trimester of pregnancy should be avoided. Continuous treatment during pregnancy and administration of high doses in connection with delivery should also be avoided. The use of benzodiazepines during the late phase of pregnancy or at delivery may require ventilation of the infant at birth.

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.

Withdrawal symptoms in newborn infants have been reported with this class of drugs.

Symptoms such as 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 it is considered as the mechanism of action.

Neonates appear to conjugate lorazepam slowly, the glucuronide being detectable in the urine for more than seven days. Glucuronidation of lorazepam may competitively inhibit the conjugation of bilirubin, leading to hyperbilirubinaemia in the newborn.

There are insufficient data regarding obstetrical safety of parenteral lorazepam, including use in caesarean section. Following caesarean section, 36% of the lorazepam patients had severe symptoms of delirium, including hallucinations, confusion, agitation, restlessness,

inappropriate weeping and repetitive hand movements. Use of intravenous lorazepam in caesarean section is not recommended.

IV or IM lorazepam administered during pregnancy was associated with significantly low Apgar scores, need for ventilation, hypothermia, and poor suckling in neonates.

The effects of lorazepam on neonates indicate that its use at any stage in pregnancy should be restricted to hospitals with facilities for neonatal intensive care.

Published animal studies of some anaesthetic/analgesic/sedation drugs have reported adverse effects on brain development in early life and late pregnancy.

Published studies in pregnant and juvenile animals demonstrate that the use of anaesthetic/analgesic and sedation drugs that block NMDA receptors and/or potentiate GABA activity during the period of rapid brain growth or synaptogenesis may result in neuronal and oligodendrocyte cell loss in the developing brain and alterations in synaptic morphology and neurogenesis when used for longer than 3 hours. These studies included anaesthetic agents from a variety of drug classes.

Use in lactation

Caution should be exercised when lorazepam is given to breast feeding women. Lorazepam is excreted in human breast milk and may cause drowsiness and feeding difficulties in the infant.

Paediatric patients may be prone to propylene glycol accumulation and toxicity (see section 4.4 Special warnings and precautions for use).

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

This medicine can impair cognitive function and can affect a patient's ability to drive safely. As with all patients taking CNS-depressant medications, patients receiving lorazepam should be warned not to operate dangerous machinery or motor vehicles until it is known that they do not become drowsy or dizzy from lorazepam therapy. Abilities may be impaired on the day following use.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

System organ class	**Very Common ≥ 1/10**	**Common ≥ 1/100 to < 1/10**	**Uncommon ≥ 1/1,000 to < 1/100**	**Frequency not known (cannot be estimated from the available data)**
Blood and lymphatic system disorders				Thrombocytopenia, agranulocytosis, pancytopenia
Immune system disorders				Hypersensitivity reactions, anaphylactic/oid reactions
Endocrine disorders				SIADH

System organ class	Very Common ≥ 1/10	Common ≥ 1/100 to < 1/10	Uncommon ≥ 1/1,000 to < 1/100	Frequency not known (cannot be estimated from the available data)
Metabolism and nutrition disorders				Hyponatremia
Psychiatric disorders		Confusion, depression, unmasking of depression	Change in libido, decreased orgasm	Disinhibition, euphoria, suicidal ideation/ attempt, paradoxical reactions, including anxiety, agitation, excitation, hostility, aggression, rage, sleep disturbances/insomnia, sexual arousal, hallucinations
Nervous system disorders[±]	Sedation, drowsiness	Ataxia, dizziness		Extrapyramidal symptoms, tremor, dysarthria/slurred speech, headache, convulsions/seizures, amnesia, coma, impaired attention/ concentration, balance disorder, disorientation, transient decorticate posturing and loss of brain-stem reflexes, akathisia.
Eye disorders				Visual disturbances (including diplopia and blurred vision)
Ear and labyrinth disorders				Vertigo
Vascular disorders				Hypotension, lowering in blood pressure, bradycardia, cardiac dysrhythmias
Respiratory, thoracic and mediastinal disorders				Respiratory depression[β], apnoea, worsening of sleep apnoea, worsening of obstructive pulmonary disease, aspiration pneumonia, worsening of asthma, difficulty handling secretions

System organ class	Very Common ≥ 1/10	Common ≥ 1/100 to < 1/10	Uncommon ≥ 1/1,000 to < 1/100	Frequency not known (cannot be estimated from the available data)
Gastrointestinal disorders			Nausea	Constipation, vomiting
Hepatobiliary disorders				Jaundice
Skin and subcutaneous tissue disorders				Angioedema, allergic skin reactions, alopecia
Musculoskeletal and connective tissue disorders		Muscle weakness		Muscle tension soreness, dystonia
Reproductive system and breast disorders			Impotence	
General disorders and administration site conditions	Fatigue	Asthenia		Hypothermia, dry mouth, hypersalivation, paradoxical reactions#, lethargy, poor co-ordination, prolonged drowsiness, extreme sedation
Investigations				Increase in bilirubin, increase in liver transaminases, increase in alkaline phosphatase

±Benzodiazepine effects on the CNS are dose-dependent, with more severe CNS depression occurring with high doses or with Drug Interaction.

βThe extent of respiratory depression with benzodiazepines is dose-dependent, with more severe depression occurring with high dose or with Drug Interaction.

#Paradoxical reactions may be more likely to occur in children and the elderly (see section 4.4 Special warnings and precautions for use).

Reporting suspected adverse effects

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://pophealth.my.site.com/carmreportnz/s/.

4.9 OVERDOSE

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

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, and especially when

other CNS-depressant drugs or alcohol are involved, symptoms may include ataxia, hypotension, hypotonia, respiratory depression, cardiovascular depression, coma and, very rarely, proves fatal.

Propylene glycol toxicity have been reported following higher than recommended doses of lorazepam.

Treatment of overdosage is mainly supportive including monitoring of vital signs and close observation of the patient. An adequate airway should be maintained and assisted respiration used as needed. Hypotension, though unlikely, may be controlled with noradrenaline. Lorazepam is poorly dialysable.

The benzodiazepine antagonist, flumazenil, may be useful in hospitalised patients for the management of benzodiazepine overdosage. Please consult the flumazenil product information prior to usage.

For advice on the management of overdose please contact the National Poisons Centre on phone number: 0800 764 766 [0800 POISON].

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Lorazepam is a benzodiazepine with anxiolytic, sedative, anticonvulsant and muscle relaxant properties.

Mechanism of action

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

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

5.2 PHARMACOKINETIC PROPERTIES

Absorption

Lorazepam Injection is readily absorbed when given intramuscularly. Peak plasma concentrations occur approximately 1-3 hours following intramuscular administration.

Distribution

At clinically relevant concentrations, lorazepam is approximately 90% bound to plasma proteins.

Metabolism

Lorazepam is metabolised in the liver, mainly to the inactive glucuronide. Seventy to seventy-five per cent of the dose is excreted as the glucuronide in the urine. The

glucuronides of lorazepam have no demonstrable CNS activities in animals, and there are no active metabolites of lorazepam.

The plasma levels of lorazepam are proportional to the dose given.

Lorazepam is not a substrate for N-dealkylating enzymes of the cytochrome P450 system nor is it hydroxylated to any significant extent.

Excretion

The elimination half-life is about 12-16 hours when given intramuscularly or intravenously.

Special patient groups

Studies comparing young and elderly subjects have shown that the pharmacokinetics of lorazepam remain unaltered with advancing age. No changes in absorption, distribution, metabolism and excretion were reported in patients with hepatic disease (hepatitis, alcoholic cirrhosis). As with other benzodiazepines, the pharmacokinetics of lorazepam may change in patients with impaired renal function and the medication should be used with caution.

Pharmacokinetics in Paediatric Patients

Children (2 Years to 12 Years)

In children with acute lymphocytic leukaemia in complete remission (2 to 12 years, n = 37), total (bound and unbound) lorazepam had a 50% higher mean volume of distribution (normalised to body-weight) and a 35% longer mean half-life compared to normal adults (n = 10). Unbound lorazepam clearance normalised to body-weight was 15% higher in children than in adults.

Adolescents (12 Years to 18 Years)

In adolescents with acute lymphocytic leukemia in complete remission (12 to 18 years, n = 13) total (bound and unbound) lorazepam had a 50% higher mean volume of distribution (normalized to body-weight) and a mean half-life that was almost two-fold greater compared to normal adults (n = 10). Unbound lorazepam clearance normalised to body-weight was comparable in adolescents and adults.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

A study of the mutagenic activity of lorazepam on *Drosophila melanogaster* indicated that this agent was mutationally inactive.

Carcinogenicity

No evidence of carcinogenic potential emerged in rats or mice during an 18-month study with oral lorazepam.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Macrogol 400, propylene glycol

6.2 INCOMPATIBILITIES

Lorazepam-AFT should not be mixed with other drugs in the same syringe.

6.3 SHELF LIFE

24 months

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store at 2 °C to 8 °C. Protect from light.

6.5 NATURE AND CONTENTS OF CONTAINER

Lorazepam-AFT solution for injection is presented in glass ampoules.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

Any unused medicine or waste material should be disposed of in accordance with local requirements.

7 MEDICINE SCHEDULE

Class C5 controlled drug

8 SPONSOR

AFT Pharmaceuticals Ltd.
PO Box 33-203, Takapuna
Auckland 0740, New Zealand

Telephone: 0800-423-823

Email: customer.service@aftpharm.com

9 DATE OF FIRST APPROVAL

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10 DATE OF REVISION

11 September 2025

Summary table of changes

Section changed	Details of change
4.9	Typographic error corrected