Abridged Prescribing Information:

Active Ingredient: Lopez ampoules contains lorazepam 2mg/ml. **Indication:** For the treatment of acute anxiety states, acute excitement or acute mania and for the control of status epilepticus. **Dosage & Administration**: Acute Anxiety - Adults:0.025-0.03mg/kg (1.75-2.1mg for an average 70kg man). Repeat 6 hourly. Lorazepam Injection is not recommended in children under 12. Status epilepticus- Adults: 4mg intravenously Paediatric population: 2mg intravenously **Contraindications:** Acute pulmonary insufficiency, Hypersensitivity to benzodiazepines, including lorazepam or to any of the excipients, Sleep apnoea syndrome, Myasthenia gravis, Severe hepatic insufficiency **Warnings & Precautions:** Prior to use, Lorazepam Injection may be diluted for IM administration and should always be diluted for IV administration with equal amounts of compatible diluent. Intravenous injection should be administered slowly except in the control of status epilepticus where rapid injection is required. The possibility that respiratory arrest may occur or that the patient may have partial airway obstruction should be considered. Therefore, equipment necessary to maintain a patent airway and to support respiration/ventilation should be available and used where necessary. The use of benzodiazepines, including lorazepam, may lead to physical and psychological dependence. Severe anaphylactic/anaphylactoid reactions have been reported with the use of benzodiazepines. Use of benzodiazepines, including lorazepam, may lead to potentially fatal respiratory depression, Concomitant use of benzodiazepines and opioids may result in sedation, respiratory depression, coma, and death. There is no evidence to support the use of Lorazepam Injection in coma or shock. Dependence may lead to withdrawal symptoms, especially if treatment is discontinued abruptly. Therefore, the drug should always be discontinued gradually - using the oral preparation if necessary. Patients with impaired renal or hepatic function should be monitored frequently and have their dosage adjusted carefully according to patient response **Pregnancy & Lactation**: There are insufficient data regarding obstetrical safety of parenteral Ativan, including use in caesarean section. Such use, therefore, is not recommended. Since benzodiazepines are found in breast milk, Ativan Injection should not be given to breast- feeding mothers unless the expected benefit to the woman outweighs the potential risk to the infant. **Interaction:** Not recommended: Concomitant intake with alcohol. 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, barbiturates, antipsychotics, sedatives/hypnotics, anxiolytics, antidepressants, narcotic analgesics, sedative antihistamines, anticonvulsants and anaesthetics ,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. Concurrent administration of lorazepam with sodium valproate may result in reduced clearance (20 to 40%) and increased concentrations of lorazepam. Concurrent administration of lorazepam with probenecid may result in reduced clearance, increased elimination half-life and increased concentrations of lorazepam, An enhancement of the euphoria induced by narcotic analgesics may occur with benzodiazepine use, leading to an increase in psychic dependence. Compounds which inhibit certain hepatic enzymes (particularly cytochrome P450) may enhance the activity of benzodiazepines. To a lesser degree this also applies to benzodiazepines which are metabolized only by conjugation. 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. Administration of theophylline or aminophylline may reduce the sedative effects of benzodiazepines, including lorazepam. There have been reports of apnoea, coma, bradycardia, heart arrest and death with the concomitant use of lorazepam injection solution and haloperidol. **Adverse Reactions:** common adverse reactions are Sedation, drowsiness Fatigue, Confusion depression, unmasking of depression, Ataxia, dizziness, Muscle weakness **Overdose:** In mild cases, symptoms include drowsiness, mental confusion and lethargy. In more serious cases, and especially when other CNS-depressant drugs or alcohol are ingested, symptoms may include ataxia, hypotension, hypotonia, respiratory depression, cardiovascular depression, coma and, very rarely, death. Propylene glycol toxicity and polyethylene glycol toxicity have been reported following higher than recommended doses of Ativan Injection. 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. *(For details, please refer full prescribing information)*

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