Abridged Prescribing Information:

Active Ingredient: LOPEZ MD 1 mg, 2 mg tablet contains Lorazepam Tablets 1 mg, 2 mg **Indication:** For the management of anxiety disorders or for the short term relief of symptoms of anxiety or anxiety associated with depressive symptoms.**Dosage & Administration**: The usual range is 2 to 6 mg/day given in divided doses, the largest dose being taken before bedtime, but the daily dosage may vary from 1 to 10 mg/day. For anxiety, most patients require an initial dose of 2 to 3 mg/day given two times a day or three times a day. For insomnia due to anxiety or transient situational stress, a single daily dose of 2 to 4 mg may be given, usually at bedtime. For elderly or debilitated patients, an initial dosage of 1 to 2 mg/day in divided doses is recommended, to be adjusted as needed and tolerated. **Contraindications:** Lorazepam is contraindicated in patients with hypersensitivity to benzodiazepines or to any components of the formulation, acute narrow-angle glaucoma **Warnings & Precautions:** Concomitant use of benzodiazepines, including Lorazepam, and opioids may result in profound sedation, respiratory depression, coma, and death. Use of benzodiazepines, including lorazepam, may lead to physical and psychological dependence. As with all patients on CNS-depressant drugs, patients receiving lorazepam should be warned not to operate dangerous machinery or motor vehicles and that their tolerance for alcohol and other CNS depressants will be diminished. In patients with depression, a possibility for suicide should be borne in mind; benzodiazepines should not be used in such patients without adequate antidepressant therapy. Lorazepam should be used with caution in patients with compromised respiratory function (e.g., COPD, sleep apnea syndrome). Elderly or debilitated patients may be more susceptible to the sedative effects of lorazepam. Paradoxical reactions have been occasionally reported during benzodiazepine use. Such reactions may be more likely to occur in children and the elderly. Should these occur, use of the drug should be discontinued. The usual precautions for treating patients with impaired renal or hepatic function should be observed. As with all benzodiazepines, the use of lorazepam may worsen hepatic encephalopathy. In patients where gastrointestinal or cardiovascular disorders coexist with anxiety, it should be noted that lorazepam has not been shown to be of significant benefit in treating the gastrointestinal or cardiovascular component. Safety and effectiveness of Lorazepam (lorazepam) in children of less than 12 years have not been established. **Pregnancy & Lactation**: Pregnancy- Because the use of these drugs is rarely a matter of urgency, the use of lorazepam during first trimester period should be avoided. Symptoms such as hypoactivity, hypotonia, hypothermia, respiratory depression, apnea, 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. Lactation-Lorazepam has been detected in human breast milk; therefore, it should not be administered to breastfeeding women, unless the expected benefit to the woman outweighs the potential risk to the infant. **Interaction:** The concomitant use of benzodiazepines and opioids increases the risk of respiratory depression because of actions at different receptor sites in the CNS that control respiration. The benzodiazepines, including Lorazepam (lorazepam), produce increased CNS-depressant effects when administered with other CNS depressants such as alcohol, barbiturates, antipsychotics, sedative/hypnotics, anxiolytics, antidepressants, narcotic analgesics, sedative antihistamines, anticonvulsants, and anesthetics. Concomitant use of clozapine and lorazepam may produce marked sedation, excessive salivation, hypotension, ataxia, delirium, and respiratory arrest. Concurrent administration of lorazepam with valproate results in increased plasma concentrations and reduced clearance of lorazepam. Lorazepam dosage should be reduced to approximately 50% when co-administered with valproate. Concurrent administration of lorazepam with probenecid may result in a more rapid onset or prolonged effect of lorazepam due to increased half-life and decreased total clearance. Lorazepam dosage needs to be reduced by approximately 50% when coadministered with probenecid. The effects of probenecid and valproate on lorazepam may be due to inhibition of glucuronidation. Administration of theophylline or aminophylline may reduce the sedative effects of benzodiazepines, including lorazepam. **Adverse Reactions:** Most frequent adverse reaction to Lorazepam was sedation (15.9%), followed by dizziness (6.9%), weakness (4.2%), and unsteadiness (3.4%). The incidence of sedation and unsteadiness increased with age.**Overdose:** Symptoms- In mild cases, symptoms include drowsiness, mental confusion, paradoxical reactions, dysarthria and lethargy. In more serious cases, and especially when other drugs or alcohol were ingested, symptoms may include ataxia, hypotonia, hypotension, cardiovascular depression, respiratory depression, hypnotic state, coma, and death. Management-General supportive and symptomatic measures are recommended. Gastric lavage may be indicated if performed soon after ingestion or in symptomatic patients. Administration of activated charcoal may also limit drug absorption.Lorazepam is poorly dialyzable. Lorazepam glucuronide, the inactive metabolite, may be highly dialyzable. The benzodiazepine antagonist flumazenil may be used in hospitalized patients as an adjunct to, not as a substitute for, proper management of benzodiazepine overdose. *(For details, please refer full prescribing information)*

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