

Abridged Prescribing Information:

Active Ingredient: DEPRAN L / 5 / H / 10 / FORTE tablets contain Escitalopram (E) + Clonazepam (C) Tablets. L: E 5 mg + C 0.25 mg; 5: E 5 mg + C 0.5 mg; H: E 10 mg + C 0.25 mg; 10: E 10 mg + C 0.5 mg; FORTE: E 20 mg + C 0.5 mg

Indication: Treatment of major depressive disorder associated with anxiety. **Dosage & Administration:** In major depressive disorder (MDD) and associated anxiety, treatment should be initiated with one tablet of DEPRAN H or DEPRAN 10 daily. Because both 10 mg and 20 mg per day doses of escitalopram are effective, if a dosage exceeding 10 mg escitalopram daily is considered necessary, one tablet of DEPRAN FORTE or two tablets of DEPRAN H daily can be started after a minimum of 1 week. If a stronger anxiolytic effect is desired, two tablets of DEPRAN 10 daily can be given in place of one tablet of DEPRAN FORTE. **Contraindications:** History of sensitivity to clonazepam and/or escitalopram, clinical or biochemical evidence of significant liver disease, acute narrow angle glaucoma. **Warnings & Precautions:** Clinical Worsening and Suicide Risk, Risk of Serotonin Syndrome, Impairment of Motor Performance. To avoid withdrawal symptoms reported to occur on abrupt discontinuation of the SSRI and SNRI antidepressants, DEPRAN tablets should be withdrawn by gradual dose reduction whenever possible. Escitalopram may increase the risk of bleeding events. Activation of Mania/Hypomania. Seizures, hyponatremia. **Pregnancy & Lactation:** Pregnancy category D. Nursing mothers, if taking escitalopram, should be advised not to breast-feed an infant. **Drug Interaction:** Escitalopram: Serotonergic Drugs/ MAOI -risk of serotonin syndrome. CNS Drugs - Given the primary CNS effects of escitalopram, caution should be used when it is taken in combination with other centrally acting drugs. Drugs that Interfere with Hemostasis (NSAIDs, Aspirin, Warfarin). Sumatriptan - If concomitant treatment with sumatriptan and an SSRI (e.g., fluoxetine, fluvoxamine, paroxetine, sertraline, citalopram, escitalopram) is clinically warranted, appropriate observation of the patient is advised. **Adverse Reactions:** The most common adverse events with escitalopram include nausea, ejaculation disorder, insomnia, diarrhea, somnolence, dry mouth, rhinitis, fatigue, influenza-like symptoms, dizziness and increased sweating. Prominent side effects of clonazepam are somnolence, depression, dizziness, nervousness, ataxia, and reduced intellectual ability. **Overdose:** Symptoms most often accompanying escitalopram overdose, alone or in combination with other drugs and/or alcohol, included convulsions, coma, dizziness, hypotension, insomnia, nausea, vomiting, sinus tachycardia, somnolence, and ECG changes (including QT prolongation and very rare cases of torsade de pointes). Acute renal failure has been very rarely reported accompanying overdose. **Overdose Management:** Establish and maintain an airway to ensure adequate ventilation and oxygenation. Gastric evacuation by lavage and use of activated charcoal should be considered. Careful observation and cardiac and vital sign monitoring are recommended, along with general symptomatic and supportive care. Due to the large volume of distribution of escitalopram, forced diuresis, dialysis, hemoperfusion, and exchange transfusion are unlikely to be of benefit. There are no specific antidotes for escitalopram. Symptoms of clonazepam overdosage, like those produced by other CNS depressants, include somnolence, confusion, coma, and diminished reflexes. **Overdose Management:** Treatment includes monitoring of respiration, pulse and blood pressure, general supportive measures and immediate gastric lavage. Intravenous fluids should be administered and an adequate airway maintained. Hypotension may be combated by the use of levarterenol or metaraminol. Dialysis is of no known value. Flumazenil, a specific benzodiazepine receptor antagonist, is indicated for the complete or partial reversal of the sedative effects. *(For details, please refer full prescribing information)*

Version date: 24 /02/20. If you require any further information, please reply us on productqueries@intaspharma.com