Abridged Prescribing Information:

Active Ingredient: REXIPRA contains Escitalopram Tablets 5 mg, 10 mg, 15 mg, 20 mg

Indication: For treatment of major depressive disorder & panic disorders with or without agoraphobia. **Dosage & Administration**: **Major Depressive Disorder (MDD)**: Adults and adolescents (12-17 years) - The recommended dose of escitalopram is 10 mg once daily. If a dosage exceeding 10 mg daily is considered necessary, dose may be increased to 15 mg daily after a minimum of 1 week (in adults) or 3 weeks (in adolescents). If required, dosage can be further increased to 20 mg daily (maximum recommended dose) after a minimum of 1 week (adults) or 3 weeks (adolescents). **Anxiety disorder:** Adults - The recommended dose of escitalopram is 10 mg once daily. If a dosage exceeding 10 mg daily is considered necessary, dose may be increased to 15 mg daily after a minimum of 1 week. If required, dosage can be further increased to 20 mg daily (maximum recommended dose) after a minimum of 1 week. **Discontinuation of the Treatment**: Whenever possible REXIPRA tablets should be discontinued gradually (and not abruptly) by tapering-off slowly over a period of several weeks and the patient monitored carefully to reduce the risk of withdrawal symptoms (e.g. dizziness, paraesthesia, headache, nausea, anxiety) which usually are mild and self-limiting. **Contraindication:** (1) concomitantly taking monoamine oxidase inhibitors (MAOI) or pimozide, or (2) with a hypersensitivity to escitalopram or citalopram or any of the inactive ingredients of the formulation. Starting REXIPRA in a patient who is being treated with MAOIs such as linezolid or intravenous methylene blue is also contraindicated because of an increased risk of serotonin syndrome. **Warnings & Precautions: Clinical Worsening and Suicide Risk -** Patients with major depressive disorder (MDD), both adult and pediatric, may experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality) or unusual changes in behavior, whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs. **Screening Patients for Bipolar Disorders:** A major depressive episode may be the initial presentation of bipolar disorder. Prior to initiating treatment with an antidepressant, patients with depressive symptoms should be adequately screened to determine if they are at risk of bipolar disorder; such screening should include a detailed psychiatric history, including a family history of suicide, bipolar disorder, and depression. Please note that REXIPRA tablets are not recommended for use in treating bipolar depression. **Risk of Serotonin Syndrome:** There is a risk of serotonin syndrome when escitalopram tablets are co-administered with the MAOIs. This is common to all SSRIs. **Use of Escitalopram with Other MAOIs such as Linezolid or Methylene Blue:** Do not start REXIPRA in a patient who is being treated with linezolid or intravenous methylene blue because there is an increased risk of serotonin syndrome. **Pregnancy:** There are no adequate and well-controlled studies in pregnant women; therefore, escitalopram should not be used during pregnancy unless clearly necessary and only after careful consideration of the risk versus benefit. **Specific Population: Elderly / Patients with Hepatic Impairment:** 10 mg/day is the recommended dose for most elderly patients and patients with hepatic impairment. No dosage adjustment is necessary for patients with mild or moderate renal impairment. REXIPRA tablets should be used with caution in patients with severe renal impairment. **Adverse Reactions:** Escitalopram has a predictable tolerability profile with generally mild to moderate and transient adverse events, and a low propensity for drug interactions. 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. Escitalopram demonstrated a lower incidence of nausea, increased sweating and constipation than venlafaxine extended-release (XR). **Overdose:** In clinical trials of escitalopram, there were reports of escitalopram overdose, including overdoses of up to 600 mg, with no associated fatalities. 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. 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.

(For details, please refer full prescribing information)

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