DAPRA

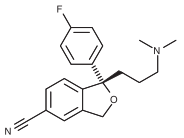
(Escitalopram)

Tablets U.S.P.

5mg
10mg
20mg

DESCRIPTION:

Dapra (Escitalopram) is an orally administered selective serotonin re-uptake inhibitor (SSRI). Escitalopram is the pure S-enantiomer (single isomer) of the racemic bicyclic phthalane derivative citalopram.



QUALITATIVE AND QUANTITATIVE COMPOSITION:

Dapra 5mg Tablets U.S.P.

Each film-coated tablet contains:

Escitalopram Oxalate U.S.P. eq. to Escitalopram.....5mg

Dapra 10mg Tablets U.S.P.

Each film-coated tablet contains:

Escitalopram Oxalate U.S.P. eq. to Escitalopram.....10mg

Dapra 20mg Tablets U.S.P.

Each film-coated tablet contains:

Escitalopram Oxalate U.S.P. eq. to Escitalopram.....20mg

WARNINGS: SUICIDALITY AND ANTIDEPRESSANT DRUGS

Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of Dapra or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increase in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Escitalopram is not approved for use in pediatric patients less than 12 years of age.

CLINICAL PHARMACOLOGY: Pharmacodynamics: The mechanism of antidepressant action of Dapra (Escitalopram) is to potentiation of serotonergic activity in the central nervous system resulting from its inhibition of CNS neuronal reuptake of serotonin (5-HT). Dapra (Escitalopram) is a highly selective serotonin re uptake inhibitor (SSRI) with minimal effects on norepinephrine and dopamine neuronal reuptake. Dapra (Escitalopram) is at least 100 fold more potent than the R-enantiomer with respect to inhibition of 5-HT reuptake and inhibition of 5-HT neuronal firing rate. Pharmacokinetics: The single- and multiple-dose pharmacokinetics of Dapra (Escitalopram) are linear and dose-proportional in a dose range of 10 to 30 mg/day. Biotransformation of Dapra (Escitalopram) is mainly hepatic, with a mean terminal half-life of about 27-32 hours. With once daily dosing, steady state plasma concentrations are achieved within one week. At steady state, the extent of accumulation of Dapra (Escitalopram) in plasma in young healthy subjects was 2.2-2.5 times the plasma concentrations observed after a single dose. **Absorption, Distribution & Elimination:** Following a single oral dose (20mg tablet) of Dapra (Escitalopram), peak blood levels occur at about 5 hours. Absorption of Dapra (Escitalopram) is not affected by food. The absolute bioavailability of Dapra (Escitalopram) is about 80% relative to an intravenous dose, and the volume of distribution of citalopram is about 12 L/kg. Data specific on Dapra (Escitalopram) are unavailable. The binding of Dapra (Escitalopram) to human plasma proteins is approximately 56%. Elimination of drug recovered in the urine as Dapra (Escitalopram) and S-demethylcitalopram (S-DCT) is about 8% and 10%, respectively. The oral clearance of Dapra (Escitalopram) is 600 mL/min, with approximately 7% of that due to renal clearance.

INDICATIONS AND USAGE: Dapra (Escitalopram Oxalate) is indicated for the treatment of Major Depressive Disorder & Generalized Anxiety Disorder.

DOSAGE AND ADMINISTRATION: The recommended dose of Dapra (Escitalopram) is 10 mg once daily. The dose may be increased to a maximum of 20mg daily. **Panic disorder:** 5mg daily for the first week then increasing to 10mg daily. The dose may be further increased up to a maximum of 20mg daily.

CONTRAINDICATIONS: Concomitant use in patients taking monoamine oxidase inhibitors (MAOIs) is contraindicated. Dapra (escitalopram) is contraindicated in patients with a hypersensitivity to escitalopram or citalopram or any of the inactive ingredients in Dapra (escitalopram).

WARNINGS: Potential for Interaction with Monoamine Oxidase Inhibitors:

In patients receiving serotonin reuptake inhibitor drugs in combination with a monoamine oxidase inhibitor (MAOI), there have been reports of serious, sometimes fatal, reactions including hyperthermia, rigidity, myoclonus, autonomic instability with possible rapid fluctuations of vital signs, and mental status changes that include extreme agitation progressing to delirium and coma. These reactions have also been reported in patients who have recently discontinued SSRI treatment and have been started on a MAOI. Some cases presented with features resembling neuroleptic malignant syndrome. Therefore, it is recommended that Dapra (Escitalopram) should not be used in combination with a MAOI, or within 14 days of discontinuing treatment with a MAOI. Similarly, at least 14 days should be allowed after stopping Dapra (Escitalopram) before starting a MAOI.

PRECAUTIONS: Abnormal Bleeding: Published case reports have documented the occurrence of bleeding episodes in patients treated with psychotropic drugs that interfere with serotonin reuptake. Although these studies focused on upper gastrointestinal bleeding, there is reason to believe that bleeding at other sites may be similarly potentiated. Patients should be cautioned regarding the risk of bleeding associated with the concomitant use of Dapra (Escitalopram) with NSAIDS, aspirin, or other drugs that affect coagulation. Hyponatremia: One case of hyponatremia has been reported in association with Escitalopram treatment. Patient with this event has recovered with discontinuation of Escitalopram. Seizures: Although anticonvulsant effects of racemic citalopram have been observed in animal studies, Escitalopram has not been systematically evaluated in patients with a seizure disorder. Dapra (Escitalopram) should be introduced with care in patients with a history of seizure disorder. Suicide: The possibility of a suicide attempt is inherent in major depressive disorder and may persist until significant remission occurs. Close supervision of high risk patients should accompany initial drug therapy. As with all drugs effective in the treatment of major depressive disorder, prescriptions for Dapra (Escitalopram) should be written for the smallest quantity of tablets consistent with good patient management, in order to reduce the risk of overdose. Use in Patients with Concomitant Illness: Dapra (Escitalopram) has not been systematically evaluated in patients with a recent history of myocardial infarction or unstable heart disease. In subjects with hepatic impairment, clearance of racemic citalopram was decreased and plasma concentrations were increased. The recommended dose of Dapra (Escitalopram) in hepatically impaired patients is 10 mg/day. Because Dapra (Escitalopram) is extensively metabolized, excretion of unchanged drug in urine is a minor route of elimination. Until adequate numbers of patients with severe renal impairment have been evaluated during chronic treatment with Dapra (Escitalopram), however, it should be used with caution in such patients.

DRUG INTERACTIONS: Given the primary CNS effects of escitalopram, caution should be used when it is taken in combination with other centrally acting drugs like Monoamine Oxidase Inhibitors (MAOIs). Caution is advised when concomitantly used with Serotonin re uptake inhibitors, Cimetidine, Sumatriptan, Carbamazepine, Ketoconazole and Metoprolol.

SIDE EFFECTS: Cardiovascular–Palpitation, hypertension. Infrequent: bradycardia, tachycardia, ECG abnormal, flushing, varicose vein. Central and Peripheral Nervous System Disorders-Light-headed feeling, migraine. Infrequent: tremor, vertigo, restless legs, shaking, twitching, dysequilibrium, tics, carpal tunnel syndrome, muscle contractions involuntary, sluggishness, coordination abnormal, faintness hyperreflexia, muscular tone increased. Gastrointestinal Disorders - Heartburn, abdominal cramp, gastroenteritis. Infrequent gastroesophageal reflux, bloating, abdominal discomfort, dyspepsia, increased stool frequency, belching, gastritis, hemorrhoids, gagging, polyposis gastric, swallowing difficult. General – Allergy, pain in limb, fever, hot flushes, chest pain. Infrequent: edema of extremities, chills, tightness of chest, leg pain, asthenia, syncope, malaise, anaphylaxis, fall. Hemic and Lymphatic Disorders - Bruise, anemia, nosebleed, hematoma, lymphadenopathy cervical. Metabolic and Nutritional Disorders - Increased weight. Infrequent: decreased weight, hyperglycemia, thirst, bilirubin increased, hepatic enzymes increased, gout, hypercholesterolemia. Musculoskeletal System Disorders–Arthralgia, myalgia. Infrequent: jaw stiffness, muscle cramp, muscle stiffness, arthritis, muscle weakness, back discomfort, arthropathy, jaw pain, joint stiffness. Psychiatric Disorders – Appetite increased, lethargy, irritability, concentration impaired. Infrequent: jitteriness, panic reaction, agitation, apathy, forgetfulness, depression aggravated, nervousness, restlessness aggravated, suicide attempt, amnesia, anxiety attack, bruxism, carbohydrate craving, confusion, depersonalization, disorientation, emotional lability, feeling unreal, tremulousness nervous, crying abnormal, depression, excitability, auditory hallucination, suicidal tendency. Reproductive Disorders/Female- Menstrual cramps, menstrual disorder. Infrequent: menorrhagia, breast neoplasm, pelvic inflammation, premenstrual syndrome, spotting between menses. Respiratory System Disorders - Bronchitis, sinus congestion, coughing, nasal congestion, sinus headache. Infrequent: asthma, breath shortness, laryngitis, pneumonia, tracheitis. Skin and Appendages Disorders - Rash. Infrequent: pruritus, acne, alopecia, eczema, dermatitis, dry skin, folliculitis, lipoma, furunculosis, dry lips, skin nodule. Special Senses - Vision blurred, tinnitus. Infrequent: taste alteration, ear ache, conjunctivitis, vision abnormal, dry eyes, eye irritation, visual disturbance, eye infection, pupils dilated, metallic taste. Urinary System Disorders - Urinary frequency, urinary tract infection. Infrequent: urinary urgency, kidney stone, dysuria, blood in urine.

OVERDOSAGE: 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.

PREGNANCY: Pregnancy Category -C.

NURSING MOTHERS: Racemic citalopram, like many other drugs, is excreted in human breast milk. The decision whether to continue or discontinue either nursing or therapy should take into account the risks of citalopram exposure for the infant and the benefits of Dapra (Escitalopram) treatment for the mother.

PEDIATRIC USE: Safety and effectiveness in pediatric patients have not been established.

INSTRUCTIONS: Dosage as directed by the physician. Store below 30°C. Protect from heat, light and moisture. Keep all medicines out of the reach of children. To be sold on the prescription of a registered medical practitioner only.

PRESENTATION: Dapra 5mg tablets U.S.P. are available in Alu-Alu blister pack of 1x14's with leaf insert.

Dapra 10mg tablets U.S.P. are available in Alu-Alu blister pack of 1x14's with leaf insert.

Dapra 20mg tablets U.S.P. are available in Alu-Alu blister pack of 1x14's with leaf insert.

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ISO 9001:2015 ISO 14001:2015 ISO 45001:2018

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