Nodep Tablet

نوڈیپ ٹیبلیٹ

(Escitalopram Oxalate)

COMPOSITION

Each film coated tablet contains:
Escitalopram Oxalate equivalent to 5mg of Escitalopram
Escitalopram Oxalate equivalent to 10mg of Escitalopram
Escitalopram Oxalate equivalent to 20mg of Escitalopram

DESCRIPTION

NODEP (escitalopram oxalate) is an orally administered selective serotonin reuptake inhibitor (SSRI).

CLINICAL PHARMACOLOGY

Pharmacodynamics
The mechanism of antidepressant action of escitalopram is presumed to be linked to potentiation of serotonergic activity in the central nervous system resulting from its inhibition of CNS neuronal reuptake of serotonin (5-HT). escitalopram is a highly selective serotonin reuptake inhibitor (SSRI) with minimal effects on norepinephrine and dopamine neuronal reuptake. Escitalopram has no or very low affinity for serotonergic (5-HT1-7) receptors.

Pharmacokinetics
The single- and multiple-dose pharmacokinetics of escitalopram are linear and dose-proportional in a dose range of 10 to 30 mg/day. Biotransformation of 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 approximately one week.

Absorption and Distribution
Following a single oral dose of escitalopram, peak blood levels occur at about 5 hours. Absorption of escitalopram is not affected by food.

Population Subgroups
Reduced hepatic function
Escitalopram oral clearance was reduced by 37% and half-life was doubled in patients with reduced hepatic function compared to normal subjects. 10 mg is the recommended dose of escitalopram for most hepatically impaired patients.

Reduced renal function
In patients with mild to moderate renal function impairment, oral clearance of escitalopram was reduced by 17% compared to normal subjects. No adjustment of dosage for such patients is recommended.

INDICATIONS AND USAGE

Major Depressive Disorder
NODEP is indicated for the treatment of major depressive disorder. A major depressive episode (DSM-IV) implies a prominent and relatively persistent (nearly every day for at least 2 weeks)depressed or dysphoric mood that usually interferes with daily functioning, and includes at least five of the following nine symptoms: depressed mood, loss of interest in usual activities, significant change in weight and/or appetite, insomnia or hypersomnia, psychomotor agitation or retardation, increased fatigue, feelings of guilt or worthlessness, slowed thinking or impaired concentration, a suicide attempt or suicidal ideation.

NODEP was effective in maintaining a response, in patients with major depressive disorder during an 8-week, acute-treatment phase. Nevertheless, the physician who elects to use NODEP for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient.

Generalized Anxiety Disorder
NODEP is indicated for the treatment of Generalized Anxiety Disorder (GAD).

DOSAGE AND ADMINISTRATION

Major Depressive Disorder Initial Treatment
The recommended dose of NODEP is 10 mg once daily. A fixed dose trial of NODEP demonstrated the effectiveness of both 10 mg and 20 mg of NODEP. NODEP should be administered once daily, in the morning or evening, with or without food.

Special Populations
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. NODEP should be used with caution in patients with severe renal impairment.

Treatment of Pregnant Women During the Third Trimester
When treating pregnant women with NODEP during the third trimester, the physician should carefully consider the potential risks and benefits of treatment. The physician may consider tapering NODEP in the third trimester.

Generalized Anxiety Disorder Initial Treatment
The recommended starting dose of NODEP is 10 mg once daily. If the dose is increased to 20 mg, this should occur after a minimum of one week. NODEP should be administered once daily, in the morning or evening, with or without food.

SIDE EFFECTS

Cardiovascular - Frequent: palpitation, hypertension. Infrequent: bradycardia, tachycardia, ECG abnormal, flushing, varicose vein.

CNS Disorders - Frequent: 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 - Frequent: heartburn, abdominal cramp, gastroenteritis. Infrequent: gastroesophageal reflux, bloating, abdominal discomfort, dyspepsia, increased stool frequency, belching, gastritis, hemorrhoids, gagging, polyposis gastric, swallowing difficult.

General - Frequent: 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 - Infrequent: bruise, anemia, nosebleed, hematoma, lymphadenopathy cervical.

Metabolic and Nutritional Disorders - Frequent: increased weight. Infrequent: decreased weight, hyperglycemia, thirst, bilirubin increased, hepatic enzymes increased, gout, hypercholesterolemia.

Musculoskeletal System Disorders - Frequent: arthralgia, myalgia. Infrequent: jaw stiffness, muscle cramp, muscle stiffness, arthritis, muscle weakness, back discomfort, arthropathy, jaw pain, joint stiffness.

Psychiatric Disorders - Frequent: 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.

Respiratory System Disorders - Frequent: bronchitis, sinus congestion, coughing, nasal congestion, sinus headache. Infrequent: asthma, breath shortness, laryngitis, pneumonia, tracheitis.

Skin and Appendages Disorders - Frequent: rash. Infrequent: pruritus, acne, alopecia, eczema, dermatitis, dry skin, folliculitis, lipoma, furunculosis, dry lips, skin nodule.

Special Senses - Frequent: vision blurred, tinnitus. Infrequent: taste alteration, earache, conjunctivitis, vision abnormal, dry eyes, eye irritation, visual disturbance, eye infection, pupils dilated, metallic taste.

Urinary System Disorders - Frequent: urinary frequency, urinary tract infection. Infrequent: urinary urgency, kidney stone, dysuria, blood in urine.

DRUG ABUSE AND DEPENDENCE

Escitalopram has not been systematically studied in humans for its potential for abuse, tolerance, or physical dependence. Consequently, physicians should carefully evaluate escitalopram patients for history of drug abuse and follow such patients closely, observing them for signs of misuse or abuse (e.g., development of tolerance, incrementations of dose, drug-seeking behavior).

DRUG INTERACTIONS

CNS Drugs
Given the primary CNS effects of escitalopram, caution should be used when it is taken in combination with other centrally acting drugs.

Alcohol
Although escitalopram did not potentiate the cognitive and motor effects of alcohol, the use of alcohol by patients taking escitalopram is not recommended.

Lithium
Because lithium may enhance the serotonergic effects of escitalopram, caution should be exercised when escitalopram and lithium are co-administered.

OVERDOSE

In clinical trials of racemic escitalopram, there were no reports of fatal escitalopram overdose involving overdoses of up to 2000 mg. During the postmarketing evaluation of escitalopram, like other SSRIs, a fatal outcome in a patient who has taken an overdose of escitalopram has been rarely reported.

Symptoms most often accompanying escitalopram overdose, alone or in combination with other drugs and/or alcohol, included dizziness, sweating, nausea, vomiting, tremor, somnolence, sinustachycardia, and convulsions. In more rare cases, observed symptoms included amnesia, confusion, coma, hyperventilation, cyanosis, rhabdomyolysis, and ECG changes (including QTc prolongation, nodal rhythm, ventricular arrhythmia, and one possible case of Torsades de pointes).

CONTRAINDICATIONS

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

PRESENTATION

NODEP tablets are available as:
5mg in the blister pack of 2 X 7's tablets
10 mg in the blister pack of 2 X 7's tablets
20mg in the blister pack of 2 X 7's tablets

INSTRUCTIONS

To be sold on the prescription of a registered medical practitioner only.
Avoid exposure to heat and light.
Stored below 30°C.
Keep out of the reach of children.

ہدایات:
صرف معتمد ڈاکٹر کے نسخے پر فروخت کریں۔
دوا کو دھوپ اور گرمی سے بچائیں۔
۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
بچوں کی پہنچ سے دور رکھیں۔
خوراک:
ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

Manufactured by:

OBS

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