NEPTINE TABLETS

(Paroxetine Hydrochloride 20 mg)

COMPOSITION

Each tablet contains paroxetine hydrochloride equivalent to 20 mg paroxetine.

DESCRIPTION AND PHARMACOLOGY

Paroxetine is a selective serotonin reuptake inhibitor (SSRI) antidepressant. It selectively inhibits neuronal reuptake of serotonin (5-hydroxytryptamine, 5-HT) in the central nervous system and thereby increases serotonergic activity. It has little affinity for muscarinic, histamine or adrenergic receptors.

INDICATIONS

In adults, paroxetine is used for major depressive disorder, obsessive-compulsive disorder (OCD), panic disorder with or without agoraphobia, social anxiety disorder, generalized anxiety disorder and post-traumatic stress disorder, according to the locally approved indications.

DOSAGE AND ADMINISTRATION

For oral administration under medical supervision. Usually taken once daily, preferably in the morning; may be taken with food. Dosing varies by diagnosis and patient response.

Depression: Usually 20 mg once daily initially; may be increased by 10 mg increments at intervals of at least one week, to a maximum of 50 mg daily.

OCD: Start at 20 mg daily; usual target 40 mg daily; maximum 60 mg daily.

DOSAGE AND ADMINISTRATION (cont.)

Panic disorder: Start at 10 mg daily to reduce early symptom worsening; usual target 40 mg daily; maximum 60 mg daily.

Social anxiety and generalized anxiety: Common starting dose 20 mg daily; adjust only on prescriber advice.

PTSD: Start at 20 mg daily; may be increased in 10 mg steps to a maximum of 50 mg daily.

Older adults and significant kidney or liver impairment: Lower starting doses and lower maximum doses may be required. A 20 mg tablet may not permit the recommended 10 mg initiation unless an appropriately approved divisible formulation is available.

Continue treatment for the clinically indicated period. Do not abruptly stop treatment; gradual dose reduction is recommended to limit discontinuation symptoms.

CONTRAINDICATIONS

Hypersensitivity to paroxetine or any component; concomitant or recent use of monoamine oxidase inhibitors (MAOIs), including linezolid or intravenous methylene blue; concomitant use of thioridazine or pimozide. Observe recommended washout periods when changing between paroxetine and MAOIs.

IMPORTANT WARNINGS

Suicidal thoughts and behavior: Antidepressants may increase suicidal thinking and behavior in children, adolescents and young adults, particularly when starting therapy or changing dose. Monitor for worsening depression, agitation, behavioral changes or suicidality. Seek urgent medical help if these occur. Paroxetine is not approved for pediatric use.

WARNINGS AND PRECAUTIONS (cont.)

Serotonin syndrome: Potentially life-threatening, especially with other serotonergic medicines. Symptoms include agitation, fever, sweating, tremor, diarrhea, hyperreflexia and muscle rigidity. Discontinue and seek immediate care if suspected.

Bleeding: SSRIs may increase bruising and bleeding, particularly with aspirin, NSAIDs or anticoagulants.

Other precautions: Screen for bipolar disorder before use; mania/hypomania, seizures, hyponatremia (SIADH), angle-closure glaucoma in predisposed patients, akathisia and sexual dysfunction can occur. Use caution in elderly patients or those at increased fall risk.

DRUG INTERACTIONS

Do not combine with MAOIs, thioridazine or pimozide. Other serotonergic agents (including tramadol, triptans, lithium, St John's wort and some opioids) increase serotonin syndrome risk. Warfarin, other anticoagulants, aspirin and NSAIDs increase bleeding risk. Paroxetine strongly inhibits CYP2D6 and may reduce activation and effectiveness of tamoxifen; discuss alternatives. Alcohol may impair functioning and should be avoided.

PREGNANCY

Paroxetine use during pregnancy may be associated with fetal risks, including cardiovascular malformations after first-trimester exposure, and neonatal adaptation problems or persistent pulmonary hypertension with late exposure. Use only after individual assessment of benefits and risks; do not stop treatment suddenly without medical advice.

LACTATION

Paroxetine is excreted in breast milk in small amounts. A clinician should evaluate benefit and risk and monitor breastfed infants when relevant.

ADVERSE REACTIONS

Commonly reported effects include nausea, dry mouth, sweating, dizziness, somnolence or insomnia, tremor, headache, constipation or diarrhea, decreased appetite and sexual dysfunction (including reduced libido, delayed ejaculation or anorgasmia).

Serious effects requiring medical attention include suicidal thinking, serotonin syndrome, significant bleeding, seizures, severe hyponatremia, mania, severe allergic reaction and visual pain or acute glaucoma symptoms.

DISCONTINUATION SYMPTOMS

Abrupt withdrawal can cause dizziness, sensory disturbances (including electric-shock sensations), sleep disturbance, anxiety, agitation, nausea, headache and sweating. Reduce the dose gradually under clinical supervision; tapering may need to be slow.

OVERDOSAGE

Symptoms may include nausea, vomiting, tremor, agitation, rapid heart rate, drowsiness and potentially serious serotonin toxicity or cardiac effects. Seek emergency medical care. Treatment is supportive with monitoring; there is no specific antidote.

DRIVING AND MACHINERY

Dizziness, sleepiness or impaired concentration may occur. Avoid driving or operating hazardous machinery until the individual response is known.

STORAGE CONDITIONS

Store in a cool, dry place, protected from excess heat and moisture, according to the approved pack labeling. Keep out of reach of children.

PRESENTATION

Neptine Tablets 20 mg: pack of 10 tablets.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.