SETALIN TABLETS

(Sertraline Hydrochloride 50 mg & 100 mg)

COMPOSITION

Each Setalin 50 mg tablet contains Sertraline Hydrochloride equivalent to Sertraline 50 mg. Each Setalin 100 mg tablet contains Sertraline Hydrochloride equivalent to Sertraline 100 mg. Excipients: as per approved formulation.

DESCRIPTION & PHARMACOLOGY

Sertraline is a selective serotonin reuptake inhibitor (SSRI) antidepressant. It selectively inhibits neuronal reuptake of serotonin (5-HT), increasing serotonergic activity in the central nervous system. Its antidepressant and anxiolytic effects develop progressively with continued treatment.

INDICATIONS

Sertraline is indicated for major depressive disorder (MDD), obsessive-compulsive disorder (OCD), panic disorder, post-traumatic stress disorder (PTSD), social anxiety disorder and premenstrual dysphoric disorder (PMDD), subject to locally approved indications.

DOSAGE AND ADMINISTRATION

For oral administration once daily, in the morning or evening, with or without food. Dosage should be individualised by the prescribing physician. **Adults:** MDD and OCD: usual starting dose 50 mg once daily. Panic disorder, PTSD and social anxiety disorder: start with 25 mg once daily for one week, then 50 mg daily. Dose may be increased in steps of 25-50 mg at intervals of at least one week, based on response and tolerability; maximum 200 mg/day.

ADDITIONAL DOSAGE GUIDANCE

For PMDD, continuous treatment generally starts at 50 mg daily (maximum 150 mg/day); intermittent luteal-phase treatment generally starts at 50 mg daily (maximum 100 mg/day). Follow indication-specific titration guidance. Setalin tablets are supplied only in 50 mg and 100 mg strengths; lower prescribed starting doses require an appropriate suitable dosage form. Do not abruptly discontinue; taper gradually under medical advice.

PAEDIATRIC USE

For OCD only, approved sertraline dosing may begin at 25 mg daily for children 6-12 years and 50 mg daily for adolescents 13-17 years; specialist supervision is essential. The appropriate strength is required for 25 mg initiation. Safety and efficacy for other paediatric indications are not established in the referenced label.

ELDERLY & ORGAN IMPAIRMENT

Use caution in elderly patients due to increased risk of hyponatraemia. For mild hepatic impairment, use half the usual starting and maximum doses; use in moderate or severe hepatic impairment is not recommended. Renal impairment usually does not require dose adjustment, but clinical monitoring is appropriate.

CONTRAINDICATIONS

Hypersensitivity to sertraline or any excipient; concomitant use with monoamine oxidase inhibitors (MAOIs), including linezolid or intravenous methylene blue, or within relevant washout periods; concomitant pimozide. Allow at least 14 days between stopping an MAOI and starting sertraline, and at least 14 days after stopping sertraline before starting an MAOI.

WARNINGS & PRECAUTIONS

Suicidality: Antidepressants may increase suicidal thoughts and behaviour in children, adolescents and young adults, especially early in treatment or after dose changes. Observe closely for worsening mood, agitation or unusual behaviour. **Serotonin syndrome:** Potentially life-threatening syndrome can occur with sertraline alone or combined with other serotonergic medicines; symptoms may include fever, confusion, agitation, tremor, muscle rigidity, diarrhoea and autonomic instability. Discontinue and obtain urgent care if suspected.

OTHER IMPORTANT PRECAUTIONS

Sertraline may increase bleeding risk, especially with NSAIDs, aspirin, antiplatelets and anticoagulants. Screen for bipolar disorder; mania/hypomania may occur. Use cautiously with seizure disorders, risk factors for QT prolongation, and untreated anatomically narrow angles (angle-closure glaucoma). Hyponatraemia/SIADH may occur, particularly in elderly patients or those taking diuretics. Sexual dysfunction and withdrawal symptoms may occur. Avoid alcohol if it impairs judgement or function.

DRUG INTERACTIONS

Do not combine with MAOIs or pimozide. Monitor closely with triptans, tramadol, lithium, fentanyl, buspirone, St John's wort, other SSRIs/SNRIs and other serotonergic drugs. Monitor anticoagulants and drugs affecting haemostasis. Sertraline may inhibit CYP2D6 and affect concentrations of some co-medications. Review all prescription and nonprescription medicines.

PREGNANCY & LACTATION

Use during pregnancy only after individual benefit-risk assessment. Exposure late in pregnancy may be associated with neonatal adaptation symptoms and persistent pulmonary hypertension of the newborn. Sertraline passes into breast milk in small amounts; assess benefit-risk and monitor infants for adverse effects. Do not stop treatment without medical consultation.

ADVERSE REACTIONS

Common adverse effects include nausea, diarrhoea/loose stools, dyspepsia, decreased appetite, tremor, increased sweating, dizziness, sleep disturbance (insomnia or somnolence), fatigue, sexual dysfunction (including decreased libido or ejaculation disorder), dry mouth and headache. Effects may be transient. Serious effects include suicidal thinking, serotonin syndrome, abnormal bleeding, severe hyponatraemia, mania, seizures, serious allergic reactions and angle-closure glaucoma; prompt medical attention is required.

OVERDOSAGE

Overdose may cause drowsiness, nausea, vomiting, tachycardia, tremor, agitation, dizziness and potentially serotonin syndrome, seizures or cardiac rhythm disturbances. Seek emergency medical care immediately. No specific antidote is available; provide supportive care and monitor vital signs and ECG as clinically indicated.

STORAGE CONDITIONS

Store in the original container, protected from excessive heat and moisture, according to approved product specifications. Keep out of reach of children. Do not use after the expiry date.

PRESENTATION

Setalin Tablets 50 mg: pack of 3 x 10 tablets. Setalin Tablets 100 mg: pack of 2 x 10 tablets. Both strengths are for oral use.

PATIENT ADVICE

Take only as prescribed. Benefit may require several weeks. Do not increase, share or stop medication without medical advice. Contact a healthcare professional promptly for severe mood changes, thoughts of self-harm or symptoms of serotonin syndrome.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.