VAXIL CAPSULES

Venlafaxine 75 mg and 150 mg
Pack size: 10 capsules

COMPOSITION

Each 75 mg capsule contains venlafaxine (as hydrochloride) equivalent to 75 mg venlafaxine. Each 150 mg capsule contains venlafaxine (as hydrochloride) equivalent to 150 mg venlafaxine. Exact salt, release system and excipients must be verified against the approved Vaxil formulation.

THERAPEUTIC CLASS

Serotonin and norepinephrine reuptake inhibitor (SNRI); antidepressant and anxiolytic.

PHARMACOLOGY

Venlafaxine and its active metabolite O-desmethylvenlafaxine inhibit neuronal reuptake of serotonin and norepinephrine, increasing their activity in the central nervous system.

IMPORTANT FORMULATION NOTE

The following dosage instructions are for **extended-release (XR) venlafaxine capsules**, which are commonly supplied in 75 mg and 150 mg strengths. Do not apply once-daily XR dosing to an immediate-release product. Confirm Vaxil's release type before printing or dispensing.

INDICATIONS

For approved extended-release venlafaxine capsules in adults: major depressive disorder, generalized anxiety disorder, social anxiety disorder and panic disorder. Use only for indications approved for Vaxil.

DOSAGE AND ADMINISTRATION

Extended-release capsules, adults: Major depression or generalized anxiety disorder: commonly start 75 mg once daily; some patients may start 37.5 mg daily for 4–7 days. Adjust according to response; usual maximum 225 mg/day. Social anxiety disorder: 75 mg once daily; higher doses have not shown added benefit. Panic disorder: often start 37.5 mg once daily for 7 days, then 75 mg daily; maximum 225 mg/day. Dose increases should generally be no more frequent than every 4 days. A 37.5 mg product may be required for initiation.

METHOD OF ADMINISTRATION

For XR capsules, take once daily with food, at approximately the same time each day. Swallow whole with water; do not divide, crush, chew or dissolve. Opening a capsule and sprinkling all intact pellets onto applesauce is allowed for certain XR products only; follow the approved Vaxil instructions. Do not stop abruptly.

RENAL AND HEPATIC IMPAIRMENT

For XR products, reduce the daily dose by about 25–50% in renal impairment and by 50% or more in severe renal impairment or dialysis. Reduce by about 50% in mild/moderate hepatic impairment, with greater reductions potentially needed in severe impairment. Individualize dosing and consult approved labeling.

CONTRAINDICATIONS

Hypersensitivity to venlafaxine, desvenlafaxine or formulation components. Concomitant use of monoamine oxidase inhibitors (MAOIs), or use within 14 days of stopping an MAOI. Allow at least 7 days after stopping venlafaxine before starting an MAOI.

BOXED WARNING: SUICIDAL THOUGHTS AND BEHAVIOURS

Antidepressants increase the risk of suicidal thoughts and behaviours in children, adolescents and young adults, particularly early in treatment and after dose changes. Closely monitor for clinical worsening, agitation, unusual behaviour or suicidal thinking. Venlafaxine is not approved for paediatric use in some jurisdictions.

SEROTONIN SYNDROME

Potentially life-threatening serotonin syndrome may occur, especially with other serotonergic medicines. Symptoms include agitation, confusion, fever, sweating, tremor, muscle rigidity, hyperreflexia and diarrhoea. Stop suspected serotonergic agents and seek urgent medical care.

WARNINGS AND PRECAUTIONS

Control hypertension before treatment and monitor blood pressure regularly. Use caution with seizure history, bipolar disorder (risk of mania/hypomania), angle-closure glaucoma risk, hyponatraemia/SIADH, bleeding disorders and elevated cholesterol. Screen for bipolar disorder before starting treatment.

DISCONTINUATION SYNDROME

Sudden stopping or rapid dose reduction may cause dizziness, sensory disturbances, insomnia, anxiety, nausea and other symptoms. Taper gradually under prescriber supervision; some patients need a prolonged taper.

DRUG INTERACTIONS

Avoid MAOIs, linezolid and intravenous methylene blue. Caution with SSRIs/SNRIs, triptans, tramadol, lithium, fentanyl, St John's wort and other serotonergic agents. NSAIDs, aspirin, anticoagulants and antiplatelet medicines may increase bleeding risk. Review medicines affecting CYP2D6 and CYP3A4.

PREGNANCY AND LACTATION

Use during pregnancy only after individualized benefit-risk assessment. Exposure late in pregnancy may cause neonatal adaptation complications and has been associated with postpartum haemorrhage risk. Venlafaxine and its active metabolite pass into breast milk; monitor breastfed infants and consult the prescriber.

ADVERSE REACTIONS

Common reactions include nausea, dry mouth, sweating, dizziness, insomnia, somnolence, constipation, reduced appetite and sexual dysfunction. Serious reactions include serotonin syndrome, hypertension, abnormal bleeding, seizures, mania, hyponatraemia and suicidal thoughts.

OVERDOSAGE

Overdose may cause tachycardia, altered consciousness, seizures, cardiac rhythm disturbances or serotonin toxicity. Seek emergency medical care immediately. Management is supportive with appropriate monitoring.

STORAGE

Store according to the approved Vaxil product label, in the original packaging and protected from moisture. Keep out of reach of children.

PRESENTATION

Vaxil Capsules 75 mg: pack of 10 capsules.
Vaxil Capsules 150 mg: pack of 10 capsules.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.