Venlalic® XL prolonged-release tablets (venlafaxine) - abbreviated prescribing information

Refer to Summary of Product Characteristics for full product information.

Presentation: Prolonged-release tablets containing 37.5 mg, 75 mg, 150 mg or 225 mg venlafaxine (as hydrochloride)

Indication:
Treatment of major depressive episodes; Prevention of recurrence of major depressive episodes; Treatment of generalised anxiety disorder; Treatment of social anxiety disorder; Treatment of panic disorder, with or without agoraphobia.

Dosage: Refer to SmPC for details and recommendations.
Major depressive episodes: Treatment should be initiated at 75 mg once daily. Patients not responding to the initial dose of 75 mg/day may benefit from higher doses up to 375 mg. Doses should be increased at intervals of around 2 weeks or more, with a minimum of 4 days between each increment. Treatment should continue for at least 6 months following remission.
Generalised anxiety disorder: The recommended starting dose is 75 mg once daily. Patients not responding to the initial dose of 75 mg/day may benefit from increased doses up to 225 mg. Doses should be increased at intervals of 2 weeks or more.
Social anxiety disorder: The recommended dose is 75 mg once daily. There is no evidence that high doses confer any additional benefit. In individual patients not responding to the initial 75 mg/day, increases up to a maximum dose of 225 mg/day may be considered. Dosage increases can be made at intervals of 2 weeks or more.
Panic disorder: The recommended dose is 37.5 mg/day for 7 days. Dosage should then be increased to 75 mg/day. Patients not responding to this dose may benefit from higher doses up to 225 mg/day. Doses should be increased at intervals of 2 weeks or more.

Contra-indications: Hypersensitivity to venlafaxine or any of the excipients, concomitant use with MAOIs, patients aged below 18 years of age, co-administration with weight loss agents.

Precautions and Warnings: Use with caution in patients with mild to moderate hepatic impairment (50% dose should be considered); renal impairment (50% dose for patients with glomerular filtration rate < 30 ml/min); raised intraocular pressure or those at risk of narrow-angle glaucoma; impaired cardiac function; a history of convulsions; predisposed to bleeding; a history of bipolar disorder; a history of aggression; patients with diabetes; patients who are pregnant (only to be administered if expected benefits outweigh any possible risk) or breast-feeding (excreted in milk and risk to the child cannot be excluded).

Close supervision of patients, and in particular those at high risk, should accompany drug therapy, especially in early treatment and following dose changes.

Driving: May impair judgment, thinking, and motor skills and therefore may affect ability to drive.

Withdrawal: Dizziness, sensory disturbances (including paraesthesia), sleep disturbances (including insomnia and intense dreams), agitation or anxiety, nausea and/or vomiting, tremor, headache and flu syndrome are the most commonly reported reactions. Generally, these events are mild to moderate and are self-limiting; however, in some patients, they may be severe and/or prolonged. It is therefore advised that when venlafaxine treatment is no longer required, gradual discontinuation by dose tapering should be carried out.

Interactions: To minimise the risk of serotonin syndrome, use with caution if venlafaxine is to be administered concomitantly with other agents that may affect the serotonergic neurotransmitter system (including triptans, SSRIs, SNRIs, lithium, sibutramine, St. John's Wort [Hypericum perforatum], fentanyl and its analogues, tramadol, dextromethorphan, tapentadol, pethidine, methadone and pentazocine), with medicinal agents that impair metabolism of serotonin (such as MAOIs e.g. methylene blue), with serotonin precursors (such as tryptophan supplements) or with antipsychotics or other dopamine antagonists

Venlalic XL prolonged-release tablets must not be used concomitantly with MAO inhibitors and at least 14 days should elapse from discontinuation of MAO inhibitors. When changing Venlalic XL prolonged-release tablets to a MAO inhibitor a pause of 7 days must occur.

Caution should also be applied in patients taking CNS-active substances, ketoconazole (CYP3A4 inhibitor), lithium, imipramine, haloperidol or metoprolol.

The use of venlafaxine with drugs that prolong the QTc interval should be avoided.

Use with caution in elderly patients.

Use with care in patients receiving anti-coagulants and platelet inhibitors.

Patients should be advised to avoid alcohol.

Side effects: Refer to SmPC for full list.

Very commonly reported: Dizziness, headache, nausea, dry mouth, hyperhidrosis.

Commonly reported: decreased appetite, confusional state, depersonalization, anorgasmia, decreased libido, nervousness, insomnia, abnormal dreams, somnolence, tremor, parasthesia, hypertonia, visual impairment including blurred vision, mydriasis, accomodation disorder, tinnitus, palpitations, hypertension, vasodilation (mostly flush), yawning, vomiting, diarrhoea, constipation, dysuria (mostly urinary hesitation), pollakiuria, menstrual disorders associated with increased bleeding or irregular bleeding (e.g. menorrhagia, metorrhagia), ejaculation disorder, erectile dysfunction, asthenia, fatigue, chills, increased blood cholesterol.

Less commonly reported: Hallucinations, derealization, agitation, abnormal orgasms (females), apathy, hypomania, bruxism, akathisia/psychomotor restlessness, syncope, myoclonus, abnormal coordination, balance disorder, dysgeusia, tachycardia, orthostatic hypotension, dyspnoea, gastrointestinal haemorrhage, angioedema, photosensitivity reaction, ecchymosis, rash, alopecia, urinary retention, weight changes.

Rarely reported: Mania, convulsions, urinary incontinence.

Also reported: thrombocytopaenia, blood disorder (including agranulocytosis, aplastic anaemia, neutropaenia, pancytopaenia), anaphylatic reaction, syndrome of inappropriate antidiuretic hormone secretion (SIADH), hyponatraemia, suicidal ideation and suicidal behaviours, delirium, aggression, neuroleptic malignant syndrome (NMS), serotonergic syndrome, extrapyramidal disorder (including dystonia and dyskinaesia), tardive dyskinaesia, angle-closure glaucoma, vertigo, ventricular fibrillation, ventricular tachycardia (including Torsade de Pointes), hypotension, bleeding (mucous membrane bleeding), pulmonary eosinophilia, pancreatitis, hepatitis, abnormal liver function test, Stevens-Johnson syndrome, erythema multiforme, toxic epidermal necrolysis, pruritus, urticaria, rhabdomyolysis, electrocardiogram QT prolongation, prolonged bleeding time, increased blood prolactin.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard
Adverse events should also be reported to Medical Services Information - enquiries@medinformation.co.uk

Price: 37.5mg x 30 - £6.60 (28's £6.16)
75mg x 30 - £11.20 (28's £10.45)
150mg x 30 - £18.70 (28's £17.45)
225mg x 30 - £33.60 (28's £31.36)

Legal category: POM

Further Information: For full prescribing information see Summary of Product Characteristics.

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