VENCARM XL (VENLAFAXINE) CAPSULE PRICE SAVINGS and GUARANTEE

Our mission is to work with the NHS to help achieve their efficiency savings goals by offering high quality branded medicines that provide significant cost savings and offer continuity for patients.*

The VENCARM® XL capsule range could save the NHS up to 79% on their current costs compared with the current Category C England and Wales Drug Tariff price for venlafaxine prolonged-release capsules and tablets.[1]

Table 1: Price of Vencarm XL capsules and venlafaxine XL **tablets** in the England and Wales Drug Tariff

Vencarm XL (28)	NHS List Price	Venlafaxine XL tablets Drug Tariff price equivalent to 28 tablets[1]		Vencarm XL difference per pack	Vencarm XL capsules % difference on price of tablets in Drug Tariff (28)[1]
37.5 mg capsules	£3.30	37.5mg	£6.16	£2.86	46%
75mg capsules	£2.59	75mg	£2.43	- £0.16	-7%
150mg capsules	£3.89	150mg	£3.64	-£0.25	-7%
225mg capsules	£9.90	225mg	£31.36	£21.46	68%

Table 2: Price of Vencarm XL capsules and venlafaxine XL **capsules** in the England and Wales Drug Tariff

Vencarm XL (28)	NHS List Price	Venlafaxine XL capsules Drug Tariff price[1]		Vencarm XL savings per pack	Vencarm XL capsules % savings on price of capsules in Drug Tariff (28)[1]
37.5 mg capsules	£3.30	37.5mg	£5.25	£1.95	37%
75mg capsules	£2.59	75mg	£2.60	£0.01	N/A
150mg capsules	£3.89	150mg	£3.90	£0.01	N/A
225mg capsules	£9.90	225mg	£47.11	£37.21	79%

We confirm that the prices will remain unchanged unless there is a material change to Category C of the England and Wales Drug Tariff or the product in the 2024 PPRS review.

If you would like any further information, please do not hesitate to contact Aspire Pharma on 01730 231148 or info@aspirepharma.co.uk.

Yours faithfully

Graham J Fraser-Pye

Graham Fraser-Pye
Managing Director

* Ensuring continuity by guaranteeing a single product is dispensed, rather than patients being dispensed a variety of generic products.

References: 1) August 2020 England and Wales Drug Tariff.

Aspire Pharma Limited
4 Rotherbrook Court Bedford Road Petersfield Hampshire GU32 3QG
T: +44 01730 231148 W: **www.aspirepharma.co.uk** E: info@aspirepharma.co.uk

Registered in England no. 6828501 Registered Address: 102 High Street Godalming Surrey GU7 1DS England

Vencarm XL (venlafaxine) Prolonged-release Capsules Prescribing Information (please refer to the full SmPC before prescribing)

Indications: Major depressive episodes (MDEs), prevention of recurrence of MDEs, generalised anxiety disorder (GAD), social anxiety disorder (SAD) and panic disorder, with or without agoraphobia. **Available strengths:** 37.5, 75, 150 and 225mg x 28 capsules. **Dosage**: MDEs: recommended starting dose 75mg once daily, if not responding, increase up to maximum 375 mg/day. GAD and SAD: recommended starting dose 75mg once daily. Panic disorder: 37.5mg/day for 7 days, then increased to 75mg/day. GAD, SAD and panic disorder patients not responding to 75mg/day increase up to maximum 225mg/day. For all indications maintain lowest effective dose; dose increases can be made at 2 weeks intervals or more; due to risk of dose-related adverse effects, only make dose increments after clinical evaluation; patients should usually be treated for several months or longer with regular reassessment. Caution in elderly. Not recommended in those under 18 years. Caution if GFR 30-70ml/min. In mild or moderate hepatic impairment, severe renal impairment (GFR < 30 ml/min) or haemodialysis reduce dose by 50%. Caution in severe hepatic impairment - reduce dose by more than 50%. Abrupt discontinuation should be avoided. Gradually reduce over several weeks/months to reduce risk of withdrawal reactions. **Administration**: Take with food, at approximately same time each day. Swallow whole with fluid - do not divide, crush, chew, or dissolve. Patients on venlafaxine immediate-release tablets may be switched to venlafaxine prolonged-release capsules at nearest equivalent daily dosage. **Contraindications:** Hypersensitivity to active substance or excipients. Concomitant treatment with irreversible monoamine oxidase inhibitors (MAOIs) due to risk of serotonin syndrome. Do not initiate for at least 14 days after discontinuation of an irreversible/reversible MAOI. Discontinue for at least 7 days before starting an irreversible/reversible MAOI. **Special warnings and precautions for use:** Monitor patients for risk of suicide-related events until improvement occurs. Monitor for clinical worsening, suicidal behaviour or changes in behaviour. Observe carefully (risk of potentially life-threatening serotonin syndrome) if given concomitantly with other serotonergic agents e.g. SSRIs, SNRIs, triptans, amphetamines, lithium, sibutramine, St John's Wort, fentanyl and analogues, tramadol, dextromethorphan, tapentadol, pethidine, methadone, pentazocine; agents that impair serotonin metabolism e.g. MAO-inhibitors, serotonin precursors e.g. tryptophan; or with antipsychotics and other dopamine antagonists, particularly during treatment initiation and dose increases. Monitor patients with raised intraocular pressure or at risk for acute narrow-angle glaucoma. Screen for high blood pressure and control pre-existing hypertension before starting treatment. Review blood pressure after starting treatment and dose increases. Caution in patients whose underlying conditions might be compromised by increases in blood pressure or heart rate, patients with recent history of myocardial infarction, unstable heart disease or at high risk of serious cardiac arrhythmia or QTc prolongation (consider risk-benefit balance). Caution if history or family history of bipolar disorder or aggression; if predisposition to bleeding, including use of anticoagulants or platelet inhibitors; if on diuretics or volume-depleted (risk of hyponatraemia/SIADH); use with caution if history of convulsions and discontinue in patients who develop seizures. Measure serum cholesterol during long-term treatment. Co-administration with weight loss agents not recommended. In patients who develop akathisia, increasing dose may be detrimental. Advise patients about importance of dental hygiene. In diabetic patients, insulin and/or oral antidiabetic dosage may need adjustment. SSRIs and SNRIs may cause symptoms of sexual dysfunction which may continue after discontinuation. **Interactions:** Must not be used with irreversible, non-selective MAOIs; concomitant treatment with reversible, selective MAOIs and linezolid not recommended. Serotonin syndrome – if concomitant treatment with SSRI, SNRI or serotonin receptor agonist (triptan) clinically warranted, carefully observe, particularly when starting treatment and dose increases. Caution when used in combination with other CNS-active substances (advise patients to avoid alcohol), CYP3A4 inhibitors, lithium, imipramine, haloperidol, metoprolol. 150mg contains Allura red (E129) and Sunset Yellow FCF (E110) and 225mg contains Carmoisine (E122), which may cause allergic reactions. Avoid co-administration with medicines prolonging QTc interval (risk of QTc prolongation/ventricular arrhythmias). Only use in pregnancy if benefits outweigh risk. Discontinuation symptoms may be seen in newborns if used before birth. Potential increased risk of persistent pulmonary hypertension in newborn. Risk to suckling child cannot be excluded – make decision to continue/discontinue breast-feeding or continue/discontinue Vencarm XL. Caution patients on their ability to drive or operate hazardous machinery. **Side effects:** For full list of side effects consult SmPC. 'Very Common' 'Common' and 'Serious' side effects included in this prescribing information. Very common (≥1/10) side effects: insomnia, headache, dizziness, sedation, nausea, dry mouth, constipation and hyperhidrosis (including night sweats). Common (≥1/100 to <1/10) side effects: decreased appetite, confusional state, depersonalisation, abnormal dreams, nervousness, libido decreased, agitation, anorgasmia, akathisia, tremor, paraesthesia, dysgeusia, visual impairment, accommodation disorder, including vision blurred, mydriasis, tinnitus, tachycardia, palpitations, hypertension, hot flush, dyspnoea, yawning, diarrhoea, vomiting, rash, pruritus, hypertonia, urinary hesitation, urinary retention, pollakiuria, menorrhagia, metrorrhagia, erectile dysfunction, ejaculation disorder, fatigue, asthenia, chills, weight decreased, weight increased, blood cholesterol increased. Uncommon (≥1/1,000 to <1/100) serious side effects: gastrointestinal haemorrhage, LFT abnormal, angioedema. Rare serious (≥1/10,000 to <1/1,000) side effects: agranulocytosis, aplastic anaemia, pancytopenia, neutropenia, anaphylactic reaction, SIADH, hyponatraemia, neuroleptic malignant syndrome (NMS), serotonin syndrome, convulsion, angle-closure glaucoma, Torsades de Pointes, ventricular tachycardia, ventricular fibrillation, ECG QT prolonged, interstitial lung disease, pancreatitis, hepatitis, Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme, rhabdomyolysis. Very rare (<1/10,000) serious side effects: thrombocytopaenia, tardive dyskinesia, mucosal haemorrhage, prolonged bleeding time. Not known (frequency cannot be estimated) serious side effects: suicidal ideation and behaviours, Stress cardiomyopathy (Takotsubo cardiomyopathy). **MA number:** PL 35533/0074-0077 **Cost:** £3.30 for 37.5mg; £2.59 for 75mg; £3.89 for 150mg and £9.90 for 225mg (x28). **MAH:** Aspire Pharma Ltd, Unit 4, Rotherbrook Court, Bedford Road, Petersfield, Hampshire, GU32 3QG. **Legal category:** POM. **Date reviewed:** August 2020. **Version number:** 1010344190 v 4.0

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 Aspire Pharma Ltd on 01730 231148

Aspire Pharma Limited
4 Rotherbrook Court Bedford Road Petersfield Hampshire GU32 3QG
T: +44 01730 231148 W: **www.aspirepharma.co.uk** E: info@aspirepharma.co.uk

Registered in England no. 6828501 Registered Address: 102 High Street Godalming Surrey GU7 1DS England