



MEDLEY PHARMACEUTICALS

D-LOX CAPSULES

(DULOXETINE)

PRESENTATION:

D-LOX is a formulation of DULOXETINE, presented in the form of enteric coated pellets enclosed in capsules.

COMPOSITION:

Each Capsule contains **DULOXETINE as HCl** (Pellets).....**40mg** (Medley's Specifications)

PHARMACOKINETICS:

Half Life ($t_{1/2}$): 12hours

Distribution: Volume of distribution (vd) is 1.640 litre and plasma protein binding occurs extensively and hepatic metabolism involves cytochrome CYP1A2 and CYP2D6.

Bioavailability: Well absorbed C_{max} 6 hours post dose. Steady state occurs after 3 days.

Excretion: Less than 1 % is excreted unchanged in urine. Of the administered dose, 70% appears in urine as metabolite and 20% in feces.

INDICATIONS:

Chronic musculoskeletal pain, diabetic peripheral neuropathic pain, fibromyalgia, generalized anxiety disorder, major depressive disorder, moderate to severe urinary incontinence in women.

DOSAGE:

Chronic Musculoskeletal pain: PO start with 40mg daily for 1 week. The dosage may be increased to 60mg once daily after 1 week.

Fibromyalgia: PO starts with 40mg once daily for 1 week. The dosage may be increased to 60mg once daily after 1 week.

Generalized Anxiety Disorder: PO start with 40mg to 80mg once daily. Additional dosage increments should be of 30mg once daily. The safety of dosage greater than 120mg once daily has not been adequately evaluated.

Major Depressive disorder: PO 40mg daily.

SPECIAL POPULATION:

Renal Function Impairment: Use a Lower starting dose and increase gradually, not recommended in patients with CrCl less than 30ml/min.

Hepatic Function Impairment: Not Recommended.



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Pregnancy: Consider tapering Duloxetine in third trimester.

ADVERSE EFFECTS:

CVS: Flushing, Palpitations, MI, Orthostatic hypotension, Peripheral coldness, Tachycardia, Hypertensive crisis, Supraventricular arrhythmias.

CNS: Headache, Somnolence, fatigue, Dizziness, Insomnia, Agitation, Decreased libido, Anxiety, Tremors, Paresthesia, Lethargy, Extrapyrimal disorders, Hallucination, Restless leg syndrome.

Dermatologic: Hyperhidrosis, Rash, Pruritus, Erythma, Steven Johnson's Syndrome, Urticaria.

EENT: Nasopharyngitis, Blurred vision, Oropharyngeal pain, Vertigo, glaucoma.

GI: Nausea, Dry Mouth, Constipation, Diarrhea, Decreased appetite, Abdominal pain, Vomiting, Dyspepsia, Flatulence.

GENITOURINARY: Erectile dysfunction, Abnormal Orgasm, Delayed ejaculation, Gynecological bleeding.

HYPERSENSITIVITY: Anaphylactic reactions, Angioneurotic edema.

METABOLIC: Decreased weight, Hyperglycemia.

CONTRAINDICATIONS:

Uncontrolled Narrow angle glaucoma, MAOI therapy.

INTERACTIONS:

Alcohol, Aspirin, NSAIDs, Warfarin, beta blockers, CNS depressants, Drugs affecting gastric acidity, Drugs highly bound to plasma protein (Phenytoin), CYP2D6 inhibitors(e.g Fluoxetine, Paroxetine, Quinidien, Terbinafine), Linezolid, MAOIs(Isocarboxazide, Rasigiline, Seligiline), Triptans (Sumatriptan).

PACKING:

Pack of 28 capsules.



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