Duloxeprin 30mg

Delayed-release Capsules

Company Name: Medizen Pharmaceutical Industries.
Pharmaceutical Form: Delayed-release capsules containing enteric coated pellets.
Generic Name: Duloxetine 30mg.
Composition:
Each capsule contains:
Active Ingredients:
Enteric coated pellets of duloxetine hydrochloride 33.7mg equivalent to duloxetine 30mg.
Inactive Ingredients:

Lactose, gelatin, hypromellose, hydroxypropyl methyl cellulose acetate succinate, sodium lauryl sulfate, sucrose, talc, titanium dioxide and triethyl citrate.

Pharmacological Action:

Duloxetine is a potent inhibitor of neuronal serotonin and norepinephrine reuptake and a less potent inhibitor of dopamine reuptake. Duloxetine does not inhibit monoamine oxidase (MAO.)
Although the exact mechanism of the antidepressant, central pain inhibitory and anxiolytic actions of duloxetine in humans are unknown, these actions are believed to be related to its potentiation of serotonergic and noradrenergic activity in the CNS.
Pharmacokinetics:

Absorption: Orally administered, duloxetine hydrochloride is well absorbed. The maximum plasma concentrations (Cmax) of duloxetine occurs 6 hours post-dose. Food does not affect the Cmax of duloxetine. Duloxetine is highly bound (>90%) to proteins in human plasma. Plasma protein binding of duloxetine is not affected by renal or hepatic impairment.
Distribution: Duloxetine has an elimination half-life of about 12 hours. Steady state plasma concentrations are achieved after 3 days of dosing. Elimination of duloxetine is mainly through hepatic metabolism.
Metabolism and Elimination: Duloxetine undergoes extensive metabolism to numerous metabolites. Only trace amounts (<1% of the dose) of unchanged duloxetine are present in the urine. Most of the duloxetine dose (about 70%) appears in the urine as metabolites. About 20% is excreted in the feces.
Indications:
1- Treatment of Major Depressive Disorder (MDD.)

2- Management of neuropathic pain associated with diabetic peripheral neuropathy.
3-Treatment of generalized anxiety disorder.

4- Stress urinary incontinence.
Dosage & Administration:
Duloxeprin should be swallowed whole and should not be chewed or crushed nor should the capsule be opened and its contents sprinkled on food or mixed with liquids. Duloxeprin is given irrelevant to meals.
Major Depressive Disorder: Duloxeprin should be administered at a total dose of 40mg/day to 60mg/day (given either once a day or as 30mg BID) irrelevant to meals.
Diabetic Peripheral Neuropathic Pain: Duloxeprin should be administered at a total dose of 60mg/day given once a day irrelevant to meals.
Generalized Anxiety Disorder: The recommended starting dose for Duloxeprin is 60mg administered once daily irrelevant to meals. For some patients, it may be desirable to start at 30mg once daily for 1 week to allow patients to adjust to the medication before increasing the dose to 60mg once daily.
Stress Urinary Incontinence: 60mg once daily**.**

Contraindications:
- Hypersensitivity to duloxetine or any of the inactive ingredients present in the drug.
- Duloxetine use was associated with an increased risk of mydriasis; therefore, its use should be avoided in patients with uncontrolled narrow-angle glaucoma. Concomitant use in patients taking

Monoamine Oxidase Inhibitors (MAOIs) is contraindicated.

Side Effects:
Nausea, dry mouth, constipation, somnolence, hyperhidrosis, decreased appetite & weight, fatigue, dizziness, tremors, hot flushes, blurred vision, insomnia, anxiety, decreased libido, erectile & ejaculatory dysfunctions, palpitations, atrial fibrillation, coronary artery disease, myocardial infarction, tachycardia & cardiac failure.

Drug Interactions:

Inhibitors of CYP1A2 & CYP2D6: Concomitant use of Duloxeprin with these potent inhibitors may result in higher concentrations of the drug in the plasma. **Drugs Metabolized by CYP2D6:** Duloxetine is a moderate inhibitor of CYP2D6. When Duloxetine was administered in conjunction with desipramine (a CYP2D6 substrate) the AUC of desipramine increased 3-folds.Therefore, co-administration of Duloxeprin with other drugs that are extensively metabolized by this isozyme, and which have a narrow therapeutic index, including certain antidepressants (tricyclic antidepressants, such as nortriptyline, amitriptyline and imipramine) & phenothiazines should be approached with caution. **Serotonergic Drugs:** Caution is advised when Duloxeprin is co administered with other drugs that may affect the serotonergic neurotransmitter systems such as triptans and linezolid.

Pregnancy and Lactation:

There are no adequate and well-controlled studies in pregnant women. Therefore, Duloxeprin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Because the safety of duloxetine in infants is not known, nursing while on Duloxeprin is not recommended.

Precautions and Warnings:
There is an increased risk of suicidal thoughts and behavior in children, adolescents and young adults taking antidepressants for Major Depressive Disorder (MDD) and other psychiatric disorders.
Duloxeprin is not approved for use in pediatric patients.

Duloxeprin increases the risk of elevation of serum transaminase levels and bilirubin. So; it should not be prescribed to patients with substantial alcohol use or evidence of chronic liver diseases.
Orthostatic hypotension and syncope have been reported with therapeutic doses of Duloxeprin. The risk of blood pressure decrease may be greater in patients taking concomitant medications that induce orthostatic hypotension (such as antihypertensives.) Blood pressure should be measured prior to initiating treatment and periodically measured throughout treatment.
Duloxeprin should be used cautiously in patients with a history of mania or seizures.
Discontinuation of Treatment with Duloxeprin: The following symptoms may occur upon discontinuation of treatment with Duloxeprin: Dizziness, nausea, headache, paresthesia, vomiting, irritability, nightmares, insomnia, diarrhea, anxiety, hyperhidrosis and vertigo. A gradual reduction in the dose, rather than abrupt cessation, is recommended to minimize the risk of these symptoms.

Package:

Carton box containing 1 or 2 pvdc/aluminum strips; each strip has 14 capsules.

Storage:
Keep out of reach of children.
Keep at a temperature not exceeding 30°C in a dry place.

Instructions for Patients:
-Keep this leaflet. You may need to read it again.
-If you have any further questions, please refer to your doctor or pharmacist.

-Do not stop this medication suddenly.

-Duloxeprin should be swallowed whole and should not be chewed or crushed nor should the contents

be sprinkled on food or mixed with liquids.

Produced by Medizen Pharmaceuticals Industries