Duloxen®

Duloxetine tablet

Presentation

Duloxen® 20: Each enteric coated delayed release tablet contains 22.45 mg of Duloxetine hydrochloride INN equivalent to 20 mg of Duloxetine.
Duloxen® 30: Each enteric coated delayed release tablet contains 33.68 mg of Duloxetine hydrochloride INN equivalent to 30 mg of Duloxetine.

Description

Duloxen (Duloxetine Hydrochloride) is a selective serotonin and norepinephrine reuptake inhibitor (SSNRI) for oral administration. Duloxetine is a less potent inhibitor of dopamine reuptake. Duloxetine has no significant affinity for dopaminergic, adrenergic, cholinergic, histaminergic, opioid, glutamate, and GABA receptors in vitro. Duloxetine does not inhibit monoamine oxidase (MAO). Orally administered Duloxetine hydrochloride is well absorbed. Elimination of Duloxetine is mainly through hepatic metabolism.

Indications and uses

Duloxen (Duloxetine Hydrochloride) is indicated for the -
01. Treatment of Major Depressive Disorder (MDD) which is associated with the following symptoms-

- depressed mood
- loss of interest in usual activities
- significant change in weight and/or appetite
- insomnia or hypersomnia
- psychomotor agitation or retardation
- increased fatigue
- feelings of guilt or worthlessness
- slowed thinking or impaired concentration
- suicide attempt or suicidal ideation

02. Management of neuropathic pain associated with diabetic peripheral neuropathy

Dosage and administration

Duloxen (Duloxetine Hydrochloride) can be taken regardless of meals.
Major Depressive Disorder (MDD): 20-30 mg bid or 60 mg once a day.
Diabetic peripheral neuropathy: A total dose of 60 mg/day given once a day.

Side effects

The most commonly observed adverse events in Duloxetine hydrochloride treated patients were nausea, dizziness, dry mouth, constipation, decreased appetite, fatigue, somnolence, increased sweating, hyperhidrosis and asthenia. It may slightly increase blood pressure. No clinically significant differences were observed for QT, PR, and QRS intervals between Duloxetine -treated and placebo-treated patients.

Precautions

Duloxetine hydrochloride should ordinarily not be prescribed to patients with substantial alcohol use. Blood pressure should be measured prior to initiating treatment and periodically measured throughout treatment. It should be used cautiously in patients with a history of mania, seizure disorder and controlled narrow-angle glaucoma.

Use in pregnancy and lactation

Pregnancy: Pregnancy Category C. There are no adequate and well-controlled studies in pregnant women; therefore, Duloxetine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
Labor and Delivery: The effect of Duloxetine on labor and delivery in humans is unknown. Duloxetine should be used during labor and delivery only if the potential benefit justifies the potential risk to the fetus.
Lactation: It is unknown whether or not Duloxetine and/or it's metabolites are excreted into human milk, but nursing while on Duloxetine is not recommended.

Use in children

Safety and efficacy in pediatric patients have not been established.

Contraindication

Duloxetine is contraindicated in patients with a known hypersensitivity to this drug or any of the inactive ingredients. Concomitant use in patients taking monoamine oxidase inhibitors (MAOIs) is contraindicated. It should be avoided in patients with uncontrolled narrow-angle glaucoma.

Drug interaction

Both CYP1A2 and CYP2D6 isozymes are responsible for Duloxetine metabolism. When Duloxetine was co-administered with fluvoxamine, a potent CYP1A2 inhibitor, the AUC ,C_{max} and $t_{}$ of Duloxetine was increased. Other drugs that inhibit CYP1A2 metabolism include cimetidine and quinolone antimicrobials such as ciprofloxacin and enoxacin would be expected to have similar effects and these combinations should be avoided. Because CYP2D6 is involved in Duloxetine metabolism, concomitant use of Duloxetine with potent inhibitors of CYP2D6 may result in higher concentrations of Duloxetine.

Overdosage

There is limited clinical experience with Duloxetine overdose in humans. There is no specific antidote to Duloxetine. In case of acute overdose, treatment should consist of those general measures employed in the management of overdose with any drug. An adequate airway, oxygenation, and ventilation should be assured, and cardiac rhythm and vital signs should be monitored. Induction of emesis is not recommended. Gastric lavage with a large-bore orogastric tube with appropriate airway protection, if needed, may be indicated if performed soon after ingestion or in symptomatic patients. Activated charcoal may be useful in limiting absorption of Duloxetine from the gastrointestinal tract.

Storage

Duloxetine tablet should be stored in a cool (15-30°C) and dry place away from light and out of the reach of children.

Patient information

Duloxetine tablet should be swallowed whole and should not be chewed or crushed, nor should the contents be sprinkled on food or mixed with liquids. All of these might affect the enteric coating. Patients should be cautioned about operating hazardous machinery including automobiles, until they are reasonably certain that Duloxetine therapy does not affect their ability to engage in such activities.

Commercial box

Duloxen® 20: Each box contains 3 blister strips of 10 enteric coated delayed release tablets.
Duloxen® 30: Each box contains 3 blister strips of 10 enteric coated delayed release tablets.

Manufactured by
Incepta Pharmaceuticals Ltd
Savar, Dhaka, Bangladesh
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DX2
V.N.02