

DURON Capsules

(Duloxetine)

ڈیوران
کپسولز
(ڈیولوکسی ٹین)

Composition:

Duron 20 mg Capsules: Each capsule contains:

Duloxetine as HCl (Pellets) 20 mg

Duron 30 mg Capsules: Each capsule contains:

Duloxetine as HCl (Pellets) 30 mg

Duron 60 mg Capsules: Each capsule contains:

Duloxetine as HCl (Pellets) 60 mg

Description:

Duloxetine is a new orally administered, balanced dual serotonin and norepinephrine (noradrenaline) reuptake inhibitor that has been developed for the treatment of stress urinary incontinence.

Pharmacodynamic Properties:

Although the exact mechanisms of the antidepressant and central pain inhibitory action of duloxetine in humans are unknown, the antidepressant and pain inhibitory actions are believed to be related to its potentiation of serotonergic and noradrenergic activity in the CNS. Preclinical studies have shown that duloxetine is a potent inhibitor of neuronal serotonin and norepinephrine reuptake and 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). Duloxetine undergoes extensive metabolism, but the major circulating metabolites have not been shown to contribute significantly to the pharmacologic activity of duloxetine.

Pharmacokinetics Properties:

Duloxetine is well absorbed by oral route. It is given once daily. Following single oral doses of duloxetine 20 mg, the time to reach C_{max} was typically in the range of 4 to 6 hours in healthy adult volunteers. Bioavailability is 50%. Volume of distribution is 10-14L/kg. Studies using ¹⁴C- labeled duloxetine indicate that the drug was highly bound to plasma proteins (>95%). It has a plasma half life of about 12 hrs. *In vitro* studies suggest that duloxetine may inhibit CYP2D6 and can be metabolized by both CYP1A2 and CYP2D6 into multiple inactive metabolites.

Indications:

1. Major depression
2. Diabetic neuropathy
3. Stress urinary incontinence

Dosage & Administration:

Major Depressive Disorder: Duron should be administered at a total dose of 40 mg/day (given as 20 mg BID) to 60 mg/day (given either once a day or as 30 mg BID) without regard to meals.

Diabetic Peripheral Neuropathic Pain: Duron should be administered at a total dose of 60 mg/day given once a day, without regard to meals. While a 120 mg/day dose was shown to be safe and effective, since diabetes is frequently complicated by renal disease, a lower starting dose and gradual increase in dose should be considered for patients with renal impairment.

Dose in renal impairment: Duloxetine is not recommended for patients with end stage renal disease.

Dose in hepatic impairment: Duloxetine is not recommended for patients with any hepatic insufficiency.

Dose for the elderly: A dose adjustment is not necessary.

Adverse Reactions:

1. Nausea
2. Central nervous system adverse effects: sleep disturbances.
3. Suicide and suicidal behavior
4. Urogenital adverse effects: obstructive voiding symptoms, acute urinary retention.
5. Cardiovascular effects: Minor and inconsistent elevations of blood pressure and heart rate.
6. Increase in hepatic enzymes such as alkaline phosphatase, alanine aminotransferase and aspartate aminotransferase.
7. Allergic reactions
8. Other adverse effects are dry mouth, constipation, decreased appetite, weight loss, fatigue, dizziness, somnolence, tremor, sweating, hot flushes, blurred vision, insomnia, anxiety.

Contraindications:

Hypersensitivity: Duron is contraindicated in patients with a known hypersensitivity to duloxetine or any of the inactive ingredients.

Monoamine Oxidase Inhibitors: Concomitant use in patients taking monoamine oxidase inhibitors (MAOIs) is contraindicated.

Uncontrolled Narrow-Angle Glaucoma: In clinical trials, Duron use was associated with an increased risk of mydriasis; therefore, its use should be avoided in patients with uncontrolled narrow-angle glaucoma.

Presentation:

Duron 20 mg Capsules: A pack of 10, 14 & 28 capsules.

Duron 30 mg Capsules: A pack of 10 capsules.

Duron 60 mg Capsules: A pack of 10, 14 & 28 capsules.



Manufactured By:
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