

# Diliner<sup>®</sup> DR

## Duloxetine

### COMPOSITION

**Diliner<sup>®</sup> DR 30** Capsule: Each capsule contains delayed release pellets of Duloxetine HCl INN equivalent to Duloxetine 30 mg.

**Diliner<sup>®</sup> DR 60** Capsule: Each capsule contains delayed release pellets of Duloxetine HCl INN equivalent to Duloxetine 60 mg.

### PHARMACOLOGY

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.

### INDICATION

- Depression
- Diabetic Peripheral Neuropathic Pain

### DOSAGE & ADMINISTRATION

#### *Major Depressive Disorder*

Duloxetine 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*

Duloxetine should be administered at a total dose of 60 mg/day given once a day, without regard to meals.

For patients for whom tolerability is a concern, a lower starting dose may be considered. 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.

### CONTRAINDICATION & PRECAUTION

Known hypersensitivity to Duloxetine.

### SIDE EFFECTS

The most commonly observed adverse events are: nausea; dry mouth; constipation; decreased appetite; fatigue; somnolence; increased sweating; dizziness and asthenia.

### DRUG INTERACTIONS

Concomitant use of duloxetine with fluvoxamine, results in approximately a 6-fold increase in AUC and about a 2.5-fold increase in C<sub>max</sub> of duloxetine. Some quinolone antibiotics would be expected to have similar effects and these combinations should be avoided.

Concomitant use of duloxetine with paroxetine, fluoxetine, quinidine increases the plasma concentration of duloxetine.

Co-administration of duloxetine with tricyclic antidepressants, phenothiazines, propafenone, flecainide should be approached with caution.

Duloxetine and thioridazine should not be co-administered.

Duloxetine may have a clinically important interaction other CNS acting drugs.

Duloxetine should be used with caution when it is taken in combination with or substituted for other centrally acting drugs, including those with a similar mechanism of action.

### STORAGE CONDITION

Store in a cool and dry place, protected from light and moisture. Keep out of the reach of children.

### HOW SUPPLIED

**Diliner<sup>®</sup> DR 30** Capsule: Each box contains 3x6 Delayed Release Capsule in blister packing.

**Diliner<sup>®</sup> DR 60** Capsule: Each box contains 3x6 Delayed Release Capsule in blister packing.

Manufactured by :



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PHARMACEUTICALS LTD.  
BANGLADESH

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