Information For the User Duloxetine (40mg) Tablet

Dulopair 40 Tablet

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Composition:

Each film-coated tablet contains:

- Duloxetine Hydrochloride I.P. equivalent to Duloxetine 40 mg
- Excipients -q.s.
- Colour: Approved colour used

Dosage Form:

Tablet

Therapeutic Category:

Serotonin and Norepinephrine Reuptake Inhibitor (SNRI) – Antidepressant

Pharmacology & Mechanism of Action:

Duloxetine is a potent selective serotonin and norepinephrine reuptake inhibitor (SNRI). It increases the levels of these neurotransmitters in the synaptic cleft by inhibiting their reuptake into the presynaptic neuron. This dual action helps alleviate symptoms of depression, anxiety, and neuropathic pain. Duloxetine also modulates pain pathways in the central nervous system, contributing to its analgesic effect.

Indications:

- Major depressive disorder (MDD)
- Generalized anxiety disorder (GAD)
- Diabetic peripheral neuropathic pain
- Fibromyalgia
- Chronic musculoskeletal pain including lower back pain and osteoarthritis
- Stress urinary incontinence (off-label use)

Dosage and Administration:

- Recommended adult dose: **40 mg to 60 mg once daily**, depending on the indication and patient response
- Dose may be adjusted as per clinical condition
- To be swallowed whole with water, without crushing or chewing
- May be taken with or without food

Contraindications:

- Hypersensitivity to duloxetine or any component of the formulation
- Concurrent use with MAO inhibitors or within 14 days of stopping an MAOI

- Uncontrolled narrow-angle glaucoma
- Severe hepatic impairment

Warnings and Precautions:

- Monitor for clinical worsening, suicidal thoughts, or unusual behavior changes, especially in young adults
- Use with caution in patients with a history of seizures, bipolar disorder, or alcohol abuse
- Monitor blood pressure periodically during therapy
- Discontinuation should be done gradually to avoid withdrawal symptoms
- Not recommended during pregnancy unless necessary; caution during lactation

Drug Interactions:

- Increased risk of serotonin syndrome when used with other serotonergic drugs (e.g., SSRIs, triptans, tramadol)
- CYP1A2 and CYP2D6 inhibitors (e.g., fluvoxamine, quinidine) may increase duloxetine levels
- Alcohol may enhance hepatotoxicity risk
- May interfere with drugs affecting coagulation; monitor when used with NSAIDs, aspirin, or anticoagulants

Adverse Effects:

- Common: Nausea, dry mouth, fatigue, dizziness, constipation, decreased appetite
- Less common: Increased blood pressure, sexual dysfunction, insomnia
- Rare: Hepatotoxicity, serotonin syndrome, orthostatic hypotension

Overdose:

Symptoms: Somnolence, serotonin syndrome, seizures, tachycardia

Treatment: Supportive care, airway management, and monitoring; no specific antidote

Storage:

Store below 25°C in a dry, cool place Protect from light and moisture

Manufactured in India for:



(An ISO 9001: 2015 Certified Co.)

Plot no.: 367-FF, Industrial Area Phase-I,

Panchkula-134113

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