FLUVATOR

For the use of a Psychiatrist or a Hospital or a Laboratory only

Abbreviated Prescribing information for FLUVATOR (Fluvoxamine 50, 100 mg Tablets) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Fluvoxamine maleate is a selective serotonin (5-HT) reuptake inhibitor (SSRI).

INDICATION: For the treatment of obsessive-compulsive disorder (OCD); treatment of depressive illness.

DOSAGE AND ADMINISTRATION: Adults, including the elderly: The recommended starting dose is 50 mg per day at bedtime. Paediatric population (children and adolescents): The recommended starting dose in paediatric populations (ages 8 to 17 years) is 25 mg administered as a single daily dose at bedtime. The tablets should be swallowed with water, without chewing.

CONTRINDICATIONS: Coadministration of tizanidine, thioridazine, alosetron, or pimozide with Fluvoxamine Maleate Tablets is contraindicated. Monoamine Oxidase Inhibitors (MAOIs) are also contraindicated due to risk of serotonin syndrome.

WARNINGS & PRECAUTIONS: Caution required for Clinical Worsening and Suicide Risk, Bipolar Disorder, Serotonin Syndrome, Angle Closure Glaucoma, Potential Thioridazine Interaction, Potential Tizanidine Interaction, Potential Pimozide Interaction, Discontinuation of treatment, Abnormal Bleeding, Mania/hypomania, Siezures, Hyponatremia, Concomitant Illness and Hepatic Impairment.

DRUG INTERACTIONS: Potential Interactions with Drugs that inhibit or are metabolized by Cytochrome P450 Isoenzymes, Other Potentially Important Drug Interactions (Benzodiazepines, Alprazolam, Diazepam, Clozapine, lithium, Methadone, Mexiletine, Ramelteon, Theophylline, Carbamazepine); CNS active drugs; Warfarin and other drugs that interfere with hemostasis (NSAIDS, aspirin, etc.); Tricyclic Antidepressants (TCAs); Other Drugs (Alosetron, Digoxin, Diltiazem, Propranolol and Other Beta-Blockers).

ADVERSE REACTIONS: Nausea, insomnia, somnolence, headache, asthenia, vomiting, nervousness, agitation and dizziness. Anorgasmia, decreased libido, dry mouth, rhinitis, taste perversion, and urinary frequency. Flu Syndrome, dysmenorrhea, flatulence, Palpitations, Diarrhea, Constipation, Dyspepsia, Dysphagia, tremor, Vasodilatation, hyperkinesia, rash, Depression, Upper Respiratory Infection, Sweating, Taste Perversion, Urinary Retention, abnormal ejaculation (mostly delayed ejaculation), anxiety, pharyngitis, impotence, myoclonus/twitch, thirst, weight loss, leg cramps, myalgia, malaise, photosensitivity reaction and suicide attempt, gastrointestinal hemorrhage and melena hemoptysis and laryngismus vaginal hemorrhage.

MARKETED BY:



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