Abridged Prescribing Information:

Active Ingredient: FREXT CR contains Fluvoxamine Maleate Extended Release Tablets 100 mg

Indication: For the treatment of obsessive compulsive disorder (OCD) and depression. **Dosage & Administration**: To treat OCD in adult patients, FREXT CR 100 is started in a dose of 100 mg (i.e., 1 tablet) once daily at bedtime. It can be taken with or without food. The dose should be increased in 50 mg increments every week, as tolerated, until maximum therapeutic benefit is achieved, up to maximum of 300 mg per day. FREXT CR 100 tablets should be swallowed whole with the aid of water, and without splitting, chewing, crushing, dissolving or damaging them anyway. **Maintenance/Continuation of Extended Treatment:** OCD patients responding to FREXT CR 100 frequently need to be maintained on the drug beyond 12 weeks. In such patients dosage adjustments should be made to maintain them on the lowest effective dosage, and they should be periodically reassessed to determine the need for continued treatment. **Discontinuation of Treatment with FREXT CR 100:** Whenever possible, FREXT CR 100 should be discontinued gradually over several weeks and not abruptly, to avoid the possibility of withdrawal syndrome. If withdrawal symptoms appear on dose reduction, then the previous dose is reinstated and subsequently dose reduction is attempted at a slower rate. **Contraindication: Hypersensitivity:** FREXT CR 100 tablets should not be given to anyone with known hypersensitivity (allergy) to fluvoxamine, or to any other ingredients present in the formulation. **Co-administration of the Following Drugs:** FREXT CR 100 tablets should not be given concurrently if a patient is receiving alosetron, tizanidine, thioridazine, pimozide, or ramelteon. Fluvoxamine blocks the hepatic metabolism of these drugs and increases the risk for serious side effects. **Monoamine Oxidase Inhibitors (MAOIs):** Concomitant use of FREXT CR 100 tablets in patients taking MAOIs or within 14 days of discontinuing MAOIs is contraindicated. **Warnings & Precautions: Clinical Worsening and Suicide Risk:** Patients with major depressive disorder (MDD), both adult and pediatric, may experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality) or unusual changes in behavior, whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs. **Screening Patients for Bipolar Disorders:** A major depressive episode may be the initial presentation of bipolar disorder. Prior to initiating treatment with an antidepressant, patients with depressive symptoms should be adequately screened to determine if they are at risk of bipolar disorder; such screening should include a detailed psychiatric history, including a family history of suicide, bipolar disorder, and depression. Please note that FREXT CR 100 is not recommended for use in treating bipolar depression. **Risk of Serotonin Syndrome:** There is a risk of serotonin syndrome when FREXT CR 100 tablets are co-administered with the MAOIs. This is common to all SSRIs. Symptoms are similar to those of neuroleptic malignant syndrome and include: hyperthermia, rigidity, myoclonus, autonomic instability, rapid fluctuations of vital signs, and mental status changes (extreme agitation, delirium, and coma). **Pregnancy:** Neonates exposed to immediate-release fluvoxamine maleate tablets and other SSRIs and SNRIs late in the third trimester have developed complications requiring prolonged hospitalization, respiratory support, and tube feeding. If receiving FREXT CR 100 in pregnancy, tapering of the medication should be considered during third trimester. While prescribing FREXT CR 100 in pregnancy, potential risks should be carefully weighed against the expected benefits. **Specific Population: Dosage for Elderly or Hepatically Impaired Patients:** In these patient groups, following the initial dose of 100 mg per day, slower upward dosage titration may be more appropriate. **Switching Patients to or from a Mono-Amine Oxidase Inhibitor (MAOI):** At least 14 days must elapse between stoppage of a MAOI and start of FREXT CR 100 or vice versa. **Adverse Reactions:** The most commonly observed adverse events associated with the use of fluvoxamine maleate extended-release capsules and likely to be drug-related (incidence 5% and at least twice that for placebo) for SAD and OCD patients were: abnormal ejaculation, anorexia, anorgasmia, asthenia, diarrhea, nausea, somnolence, sweating, and tremor. In addition, the following events were reported in the SAD patients: dyspepsia, dizziness, insomnia, and yawning. In the OCD patients, the following additional events occurred: accidental injury, anxiety, decreased libido, myalgia, pharyngitis, and vomiting. In a study evaluating immediate-release fluvoxamine maleate tablets in pediatric patients with OCD, the following additional events were observed: agitation, depression, dysmenorrhea, flatulence, hyperkinesia, and rash. **Overdose:** In case of overdosage with fluvoxamine maleate prognosis in patients may vary considerably. While ingestion of amounts as low as 1,400 mg of the drug has been fatal, that of 12,000 mg (equivalent to 2 to 3 months' dosage) has been survived. Commonly (>=5%) observed adverse events associated with fluvoxamine maleate overdose include gastrointestinal complaints (nausea, vomiting, and diarrhea), coma, hypokalemia, hypotension, respiratory difficulties, somnolence, and tachycardia. Other notable signs and symptoms seen with fluvoxamine maleate overdose (single or multiple drugs) include bradycardia, ECG abnormalities, (such as cardiac arrest, QT interval prolongation, first degree atrioventricular block, bundle branch block, and junctional rhythm), convulsions, tremor, dizziness, liver function disturbances, tremor, and increased reflexes. Treatment should consist of those general measures employed in the management of overdosage with any antidepressant.

(For details, please refer full prescribing information)

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