Abridged Prescribing Information:

Active Ingredient: FLUNIL 10 / 20/ 40 / 60 capsules contain Fluoxetine HCl 10 mg, 20 mg, 40 mg, 60 mg; Flunil Syrup- Fluoxetine HCl Suspension 20 mg/5 ml **Indication:** For the treatment of depression. **Dosage & Administration**: Adults and elderly Depression: 20 mg q.d. (usual dose), if response is inadequate after several weeks, increase dose by 20 mg/d to max. 40 mg b.i.d. (adults) or 30 mg b.i.d. (elderly) **Contraindications:** Do not use with an MAOI or within 14 days of discontinuing an MAOI due to risk of drug interaction. At least 5 weeks should be allowed after stopping Fluoxetine before treatment with an MAOI, Do not use with pimozide due to risk of drug interaction or QTc prolongation, Do not use with thioridazine due to QTc interval prolongation or potential for elevated thioridazine plasma levels. Do not use thioridazine within 5 weeks of discontinuing Fluoxetine, **Warnings & Precautions:** Clinical Worsening and Suicide Risk, Serotonin Syndrome or Neuroleptic Malignant Syndrome (NMS)-like Reactions, Allergic Reactions and Rash, Activation of Mania/Hypomania,Seizures,Altered Appetite and Weight, Abnormal Bleeding, Use with NSAIDs, aspirin, warfarin, or drugs that affect coagulation may potentiate the risk of gastrointestinal or other bleeding. Hyponatraemia, Anxiety and Insomnia, Potential for Cognitive and Motor Impairment, Use caution when operating machinery, Long Half-Life: Changes in dose will not be fully reflected in plasma for several weeks **Pregnancy & Lactation:** Pregnancy: Fluoxetine should be used during pregnancy only if the potential benefit justifies the potential risks to the fetus. Nursing Mothers: Breast feeding is not recommended **Interaction:** Monoamine Oxidase Inhibitors (MAOI): Fluoxetine is contraindicated for use with MAOI's, or within 14 days of discontinuing an MAOI due to risk of drug interaction. At least 5 weeks should be allowed after stopping fluoxetine before starting treatment with an MAOI, Pimozide: Fluoxetine is contraindicated for use with pimozide due to risk of drug interaction or QTc prolongation ,Thioridazine: Fluoxetine is contraindicated for use with thioridazine due to QTc interval prolongation or potential for elevated thioridazine plasma levels. Do not use thioridazine within 5 weeks of discontinuing Fluoxetine ,Drugs Metabolized by CYP2D6: Fluoxetine is a potent inhibitor of CYP2D6 enzyme pathway Tricyclic Antidepressants (TCAs): Monitor TCA levels during co-administration with Fluoxetine or when Fluoxetine has been recently discontinued CNS Acting Drugs: Caution should be used when taken in combination with other centrally acting drugs, Benzodiazepines: Diazepam, Antipsychotics: Potential for elevation of haloperidol and clozapine levels, Anticonvulsants: Potential for elevated phenytoin and carbamazepine levels and clinical anticonvulsant toxicity, Serotonergic Drugs: Potential for Serotonin Syndrome,Triptans: There have been rare post marketing reports of Serotonin Syndrome with use of an SSRI and a triptan,Tryptophan: Concomitant use with tryptophan is not recommended,Drugs that Interfere with Hemostasis (e.g. NSAIDs, Aspirin, Warfarin): May potentiate the risk of bleeding,Drugs Tightly Bound to Plasma Proteins: May cause a shift in plasma concentrations, **Adverse Reactions**: Most common adverse reactions (≥5% and at least twice that for placebo) associated with: Major Depressive Disorder, Obsessive Compulsive Disorder, Bulimia, and Panic Disorder: abnormal dreams, abnormal ejaculation, anorexia, anxiety, asthenia, diarrhea, dry mouth, dyspepsia, flu syndrome, impotence, insomnia, libido decreased, nausea, nervousness, pharyngitis, rash, sinusitis, somnolence, sweating, tremor, vasodilatation, and yawn **Overdose:** Treatment should consist of those general measures employed in the management of overdosage with any drug effective in the treatment of Major Depressive Disorder. Ensure an adequate airway, oxygenation, and ventilation. Monitor cardiac rhythm and vital signs. General supportive and symptomatic measures are also recommended. Induction of emesis is not recommended. (For details, please refer full prescribing information)

Version date: 10/03/21. If you require any further information, please reply us on productqueries@intaspharma.com