Prolert®
Fluoxetine

COMPOSITION
Prolert® Capsule: Each capsule contains Fluoxetine 20 mg as Fluoxetine Hydrochloride BP.
Prolert® Oral Solution: Each 5 ml oral solution contains Fluoxetine 20 mg as Fluoxetine Hydrochloride BP.

PHARMACOLOGY
Prolert® has been shown to selectively inhibit the reuptake of serotonin at the presynaptic neuronal membrane which causes increased synaptic concentration of serotonin in the CNS. This result in numerous functional changes associated with enhanced serotonergic neurotransmission. **Prolert®** appears to have no effect on the reuptake of norepinephrine and dopamine and does not exhibit anticholinergic, antihistaminic or α1 adrenergic blocking activity at usual therapeutic doses.

INDICATIONS
a) Major Depressive Disorder b) Obsessive Compulsive Disorder c) Bulimia Nervosa d) Panic Disorder.

DOSAGE AND ADMINISTRATION
Major Depressive Disorder: Adults: The recommended starting dose is 20 mg/day. Paediatric (8-18 years): The recommended starting dose is 10-20 mg/day.
Obsessive compulsive Disorder: Adults: The recommended starting dose is 20 mg/day. Paediatric (7-18 years): The recommended starting dose is 10 mg/day.
Bulimia Nervosa: A dose of 60mg/day is recommended. Panic Disorder: Initial dose is 10 mg/day.

CONTRAINDICATION AND PRECAUTION
a) Patient taking Monoamine Oxidase inhibitors b) Severe renal failure c) Nursing mothers and d) Hypersensitivity to Fluoxetine. Fluoxetine should be discontinued in any patient who develops seizures. Fluoxetine should be avoided in patients with unstable epilepsy. Alternate day dosing of Fluoxetine is recommended in patients with mild to moderate renal failure. Fluoxetine may alter glycemic control in diabetic patients. Insulin and/or oral hypoglycemic dosage may need to be adjusted. Fluoxetine should be discontinued upon the appearance of rash or of other allergic phenomena for which an alternative etiology cannot be identified.

SIDE EFFECT
Serious side-effect of Fluoxetine is rare. The most commonly observed adverse events are nervousness, nausea and insomnia, drowsiness, tremor, sweating, diarrhoea and dizziness or light headedness. Other side effects include impotence and decreased libido.

OVERDOSE
Nausea and vomiting is prominent in overdoses. Other prominent symptoms of overdose include agitation, restlessness, hypomania and other signs of CNS excitation. Reports of death attributed to overdose of Fluoxetine alone have been extremely rare.

DRUG INTERACTION
MAO inhibitors: Sometimes serious fatal reactions have been reported with concomitant use. Antidepressants: There have been greater than two fold increases of previously stable plasma levels of other antidepressants. Lithium: There have been reports of increased or decreased lithium levels when used concomitantly with Fluoxetine. Antipsychotics: Elevation of blood levels of haloperidol and clozapine has been observed in patients receiving concomitant Fluoxetine. Anticonvulsants: Patients on stable dose of phenytoin and carbamazepine have developed elevated plasma anticonvulsant concentrations and clinical anticonvulsant toxicity following initiation of concomitant fluoxetine treatment. CNS active drugs: Caution is advised if concomitant administration of Fluoxetine is required.

USE IN PREGNANCY & LACTATION
Pregnancy: Pregnancy category C. It can be used during pregnancy only if the potential benefit justifies the potential risks to the fetus. Lactation: The use of Fluoxetine in lactation is not recommended.

STORAGE CONDITION
Protect from light. Store below 30° C. Keep out of the reach of children.

HOW SUPPLIED
Prolert® Capsule: Each box contains 50 capsules in blister pack.
Prolert® Oral Solution: Each PET bottle contains 50 ml oral solution with measuring cup.

Manufactured by
SQUARE
PHARMACEUTICALS LTD.
Pabna, Bangladesh