

# Prolert<sup>®</sup>

## Fluoxetine

### COMPOSITION

**Prolert<sup>®</sup>** Capsule: Each capsule contains Fluoxetine 20 mg as Fluoxetine Hydrochloride BP.

### PHARMACOLOGY

**Prolert<sup>®</sup>** 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<sup>®</sup>** appears to have no effect on the reuptake of norepinephrine and dopamine and does not exhibit anticholinergic, antihistaminic or  $\alpha 1$  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

Risk of suicidal thinking and change of behavior.

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.

### 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 & moisture. Keep in cool & dry place. Store below 30° C. Keep all the medicines out of the reach of children.

### HOW SUPPLIED

**Prolert<sup>®</sup>** Capsule: Each box contains 50 capsules in blister pack.

Manufactured by



**SQUARE**  
PHARMACEUTICALS LTD.  
BANGLADESH