



**Prolert®**

Fluoxetine  
**Antidepressant**

### COMPOSITION

Prolert® capsule : Each capsule contains Fluoxetine Hydrochloride BP equivalent to 20 mg Fluoxetine BP.

### PHARMACOLOGY

Prolert® (Fluoxetine Hydrochloride) is a phenylpropylamine derivative antidepressant for oral administration, it is chemically unrelated to tricyclic, tetracycline or other available antidepressants.

Prolert® has been shown to selectively inhibit the reuptake of serotonin (5-HT) at the presynaptic neuronal membrane which causes increased synaptic concentration of serotonin in the CNS. This results 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 antihistaminic or  $\alpha_1$  adrenergic blocking activity at usual therapeutic doses.

### INDICATION

- a) Depressive illness
- b) Bulimia nervosa and anorexia nervosa
- c) Obsessive compulsive disorders
- d) Pre-menstrual syndrome

### DOSAGE AND ADMINISTRATION

Prolert® is administered orally to adults only ; without regard to meals.

**Depression:** *Adults and elderly:* A dose of 20 mg/day is recommended.

**Bulimia nervosa:** *Adults and elderly:* A dose of 60 mg/day is recommended.

**Obsessive compulsive disorder:** The recommended starting dose is 20 mg/day which can be gradually increased to 60 mg/day. In **pre-menstrual syndrome**, usual dose is 20 mg/day or as directed by the physician.

*Children:* The use of Prolert® in children is not recommended as safety and efficacy have not been established.

### CONTRAINDICATION AND PRECAUTION

- a) Monoamine Oxidase inhibitors
- b) Severe renal failure
- c) Usage in nursing mothers
- d) Hypersensitivity to Fluoxetine

Prolert® should be discontinued in any patient who develops seizures. Prolert® should be avoided in patients with unstable epilepsy. Alternate day dosing of Prolert® is recommended in patients with mild to moderate renal

CNS PREPARATIONS

## Prolert®

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failure. Prolert® may alter glycaemic control in diabetic patients. Insulin and/or oral hypoglycaemic dosage may need to be adjusted.

Prolert® should be discontinued upon the appearance of rash or of other allergic phenomena for which an alternative aetiology cannot be identified.

*Warning:* Prolert® is not recommended for children. Prolert® should not be prescribed in pregnancy and lactation.

### **SIDE EFFECT**

Serious side-effect of Prolert® is rare. The most commonly observed adverse events are nervous system complaints, including anxiety, nervousness and insomnia; drowsiness and fatigue or asthenia; tremor; sweating; gastrointestinal complaints, including anorexia, nausea and diarrhoea; and dizziness or light headedness. Other side effects include angioedema, urticaria, or other allergic reactions.

*Acute 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 (Prolert®) alone have been extremely rare.

### **DRUG INTERACTION**

*MAO inhibitors:* Serious sometimes fatal reactions have been reported with concomitant use. *Tryptophan:* Patients experience adverse reactions including agitation, restlessness, and GI distress. *Other 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 (Prolert).

Concomitant use of Prolert with another drug which highly protein bound (e.g. warfarin, digitoxin) may cause a transient shift in plasma concentration possibly resulting in adverse effects. *CNS active drugs:* Caution is advised if concomitant administration of Prolert is required.

### **USE IN PREGNANCY AND LACTATION**

Prolert® should not be prescribed in pregnancy and lactation.

### **HOW SUPPLIED**

Prolert®: Box containing 5 x 10 capsules in milky white opaque blister pack.

