PROSUN

Fluoxetine 10/20 mg Tablet

GENERIC NAME: Fluoxetine HCl

PHARMACOLOGICAL CLASS: Selective serotonin reuptake inhibitor

THERAPEUTIC CLASS: Antidepressant

COMPOSITION AND PRESENTATION:

PROSUN 10

Composition

Each tablet contain Fluoxetine HCl equiv. to Fluoxetine 10 mg

Presentation

30 Tablets X 5 Blisters

PROSUN 20

Composition

Each tablet contain Fluoxetine HCl equiv. to Fluoxetine 20 mg

Presentation

30 Tablets X 5 Blisters

MECHANISM OF ACTION

Fluoxetine is in the class of antidepressants called selective serotonin reuptake inhibitors (SSRIs).The antidepressant, antiobsessive-compulsive, and antibulimic actions of fluoxetine are supposed to be linked to its inhibition of CNS neuronal uptake of serotonin. Studies in man have demonstrated that fluoxetine blocks the uptake of serotonin into human platelets.

INDICATIONS:

- Major Depression
- Obsessive Complusary Disorder
- Premenustral Dysphoric Disorder
- Panic Disorder

DOSAGE:

10-20 mg once daily

PHARMACOKINETICS:

Absorption:

Following a single oral 40 mg dose, peak plasma concentrations of fluoxetine from 15 to 55 ng/mL are observed after 6 to 8 hours.Food does not appear to affect the systemic bioavailability of fluoxetine, although it may delay its absorption by 1 to 2 hours, which is probably not clinically significant. Thus, fluoxetine may be administered with or without food.

Protein Binding

Over the concentration range from 200 to 1000 ng/mL, approximately 94.5% of fluoxetine is bound *in vitro* to human serum proteins, including albumin and α1-glycoprotein.

Metabolism

Fluoxetine is extensively metabolized in the liver to norfluoxetine and a number of other unidentified metabolites

Excretion:

The relatively slow elimination of fluoxetine (elimination half-life of 1 to 3 days after acute administration and 4 to 6 days after chronic administration) and its active metabolite, norfluoxetine (elimination half-life of 4 to 16 days after acute and chronic administration), leads to significant accumulation of these active species in chronic use and delayed attainment of steady state, even when a fixed dose is used.

Adverse effects:

- **CNS:** anxiety, drowsiness, headache, insomnia, abnormal dreams, dizziness, fatigue, nervousness, hypomania, mania, weakness, tremor, **seizures, suicidal ideation**
- **CV:** chest pain, palpitations, **prolonged QTc interval**
- **EENT:** visual disturbances, stuffy nose, sinusitis, pharyngitis
- **GI:** nausea, vomiting, diarrhea, constipation, abdominal pain, dyspepsia, dry mouth, anorexia
- **GU:** urinary frequency, sexual dysfunction, dysmenorrhea
- **Metabolic:** hypouricemia, hypocalcemia, hyponatremia, hyperglycemia, **hypoglycemia**
- **Musculoskeletal:** joint, back, or muscle pain
- **Respiratory:** cough, upper respiratory tract infection, dyspnea, **respiratory distress**
- **Skin:** diaphoresis, pruritus, erythema nodosum, flushing, rash
- **Other:** abnormal taste, weight loss, fever, flulike symptoms, hot flashes, allergic reactions, hypersensitivity reactions

PRECAUTIONS:

Use cautiously in:

- hepatic or renal impairment, diabetes mellitus, cardiovascular disease
- history of seizures
- pregnant or breastfeeding patients.

CONTRAINDICATIONS:

- Hypersensitivity to drug
- MAO inhibitor use within past 14 days

DRUG INTERACTIONS:

- **Adrenergics***:* increased sensitivity to adrenergics, increased risk of serotonin syndrome
- **Alprazolam:** decreased metabolism and increased effects of alprazolam
- **Antihistamines, opioids, other antidepressants, sedative-hypnotics***:* additive CNS depression
- **Buspirone:** potentiation of fluoxetine effects, increased risk of seizures
- **Carbamazepine, clozapine, digoxin, haloperidol, lithium, phenytoin, warfarin***:* increased blood levels of these drugs, greater risk of adverse reactions
- **CYP450-2D6 inducers***:* increased effects of these drugs
- **Cyproheptadine:** decrease in or reversal of fluoxetine effects
- **Digoxin, warfarin, other highly protein-bound drugs***:* increased risk of adverse reactions to either drug
- **Efavirenz, ritonavir, saquinavir, other CYP450 inhibitors***:* increased risk of serotonin syndrome
- **MAO inhibitors***:* confusion, agitation, seizures, hypertension, and hyperpyrexia (serotonin syndrome)
- **Other antidepressants, phenothiazines, risperidone, tryptophan***:* increased risk of adverse reactions
- **Ritonavir***:* increased ritonavir blood level

For further information, please contact:
Market Planning Department
Deurali-Janta Pharmaceuticals Pvt. Ltd.
GPO Box 4239, 355 Hattisar Road, Kamalpokhari, Kathmandu, Nepal.
Tel: 4435167/68/69 E-mail: mplanning@deuralijanta.com Website: www.deuralijanta.com