MedChoice
CNS

Fluoxetine
Prodin
20 mg Capsule
ANTI-DEPRESSANT

Antidepressants increase the risk of suicidal thinking and behavior (suicidality) in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders and those considering use of these agents "must balance risk with the clinical need."

FORMULATION:
Each capsule contains:
Fluoxetine (as hydrochloride), USP.....20 mg

PRODUCT DESCRIPTION:
Fluoxetine (Prodin) 20 mg is a white powder encapsulated in a hard gelatin capsule with scarlet cap and white body.

CLINICAL PHARMACOLOGY:
Pharmacodynamics:
Fluoxetine is a selective inhibitor of serotonin reuptake. It has practically no affinity to other receptors.
Pharmacokinetics:
Fluoxetine is readily absorbed from the gastrointestinal tract with peak plasma concentrations appearing about 6 to 8 hours after administration. The drug is extensively metabolized in the liver to its active metabolite norfluoxetine. It is mainly excreted via the urine. About 95% is reported to be protein-bound.
Fluoxetine is widely distributed throughout the body. The drug and its metabolite are distributed into breast milk. An elimination half-life of about 1 to 3 days is reported for Fluoxetine. Its metabolite is even longer, about 4 to 16 days. Because of these long elimination half-lives, Fluoxetine and its metabolite may persist for a considerable time after discontinuation of its use. Patients are advised to be cautious in the subsequent administration of other serotonergic antidepressants which may result to enhanced adverse effects.

INDICATIONS:
For the treatment of depression and associated anxiety, bulimia nervosa, Obsessive-Compulsive Disorder (OCD) and Premenstrual Dysphoric Disorder (PMDD).

DOSAGE AND ADMINISTRATION:
Adult:
Depression: Usual dose is 20 mg orally once daily.
Bulimia nervosa: Usual dose is 60 mg/day orally.
Obsessive-Compulsive Disorder: Initial daily dose is 20 mg orally, increased after several weeks if there is no response to up to 60 mg daily.
Premenstrual Dysphoric Disorder: Usual dose is 20 mg orally once daily. Treatment may be continued for 6 months; benefit should then be re-assessed before continuing further.
Or as prescribed by a physician.

DRUG INTERACTIONS:
Antibacterials: Rapid development of delirium was reported in a patient when Clarithromycin was added to his existing regimen of Fluoxetine.
Anticoagulants: SSRIs (Selective Serotonin Reuptake Inhibitors) which include Fluoxetine may increase the anticoagulant effects of Warfarin.
Antihistamines: Fluoxetine may increase plasma concentrations of Astemizole or Terfenadine, increasing the risk of ventricular arrhythmias; concomitant use should be avoided.
Antivirals: Plasma concentrations of Fluoxetine are possibly increased by HIV-protease inhibitors.
Anxiolytics: Fluoxetine increases plasma concentrations of some Benzodiazepines.
Beta-blockers: Bradycardia and heart block occuring shortly after introduction of treatment with Fluoxetine have been reported in patients receiving Metoprolol and Propranolol.

PRECAUTIONS:
Fluoxetine (Prodin) 20 mg capsule should be used with caution and in reduced doses in elderly patients and to those with impaired renal hepatic function. Caution should also be observed if the drug is to be used in patients with epilepsy or history of such disorders, cardiac disease or history of bleeding disorder, diabetes (since Fluoxetine may alter glycemic control), and in patients receiving concomitant ECT. Treatment with this drug should be discontinued if rash develops. Patients should be closely monitored during early therapy until improvement in depression is observed because suicide is an inherent risk in depressed patients. Since Fluoxetine may impair perfomance of skilled tasks, patients are advised not to engage in activities such as driving or operating of machinery.

CONTRAINDICATIONS:
Fluoxetine (Prodin) 20 mg capsule should not be given in severe renal or hepatic failure, uncontrolled epilepsy, pregnancy and lactation.

PREGNANCY AND LACTATION:
Use of Fluoxetine (Prodin) 20 mg capsule should be considered during pregnancy only if the potential benefit justifies the potential risk to the fetus, taking into account the risk of untreated depression. At the end of pregnancy, caution should be exercised as transitory withdrawal symptoms (e.g. transient jitteriness, difficulty feeding, tachypnea and irritability) have been reported rarely in the neonate after maternal use near term.

Fluoxetine is known to be excreted in breastmilk. Its effects on the nursing infant have not been established. If treatment with Fluoxetine (Prodin) 20 mg capsule is considered necessary, discontinuation of breast feeding should be considered.

ADVERSE EFFECTS:
Adverse effects may include dry mouth and gastrointestinal disturbances (e.g. nausea, vomiting, dyspepsia, constipation and diarrhea). Anorexia and weight loss may also occur.
Neurological side effects: Anxiety, restlessness, nervousness and insomnia, or drowsiness and fatigue; headache, tremor, dizziness, convulsions, hallucinations, extrapyramidal effects, sexual dysfunction, symptoms suggestive of a serotonin syndrome.
Hematological side effects: Purpura and bruising have been reported as the most common blood effects of Fluoxetine. Thrombocytopenia and galactorrhea have been reported.
Others: Excessive sweating, pruritus, skin rashes, urticaria, angioedema, anaphylaxis, dyspnea, pulmonary fibrosis, arthralgia and myalgia.

"For suspected adverse drug reaction, report to FDA: www.fda.gov.ph.
Seek medical attention immediately at first sign of any adverse drug reaction."

OVERDOSE AND MANAGEMENT:
Symptoms of Fluoxetine overdose may include nausea, vomiting, seizures, cardiovascular dysfunction ranging from asymptomatic arrhythmias or ECG changes indicative of QT prolongation to cardiac arrest, pulmonary dysfunction, and signs of altered CNS status ranging from excitation to coma. Fatality attributed to overdose of fluoxetine alone has been extremely rare.

Cardiac and vital signs monitoring are recommended, along with general symptomatic and supportive measures. No specific antidote is known. Forced diuresis, dialysis, hemoperfusion, and exchange transfusion are unlikely to be of benefit. Activated charcoal, which may be used with sorbitol, may be as or more effective than emesis or lavage.

In managing overdosage, consider the possibility of multiple drug involvement. An extended time for close medical observation may be needed in patients who have taken excessive quantities of a tricyclic antidepressant if they are also taking, or have recently taken, Fluoxetine (Prodin) 20 mg capsule.

CAUTION:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

STORAGE CONDITION:
Store at temperatures not exceeding 30° C.

AVAILABILITY:
Fluoxetine (Prodin) 20 mg Capsule ..... In blister pack of 10's (Box of 30's)

Registration No.: DRP-7735
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Manufactured for:
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