Prozac (fluoxetine hydrochloride) - Drug Summary

Dista Products Company

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Prozac
(fluoxetine hydrochloride)

BOXED WARNING

Antidepressants increased the risk of suicidal thoughts and behavior in children, adolescents, and young adults in short-term studies. Monitor closely for worsening and for emergence of suicidal thoughts and behaviors in patients who are started on antidepressant therapy. Not approved for use in children <7 yrs of age.

COMMON BRAND NAMES

Prozac Weekly, Prozac

THERAPEUTIC CLASS

Selective serotonin reuptake inhibitor (SSRI)

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Major Depressive Disorder

Initial: 20mg/day qam
Titrate: Consider a dose increase after several weeks if improvement is insufficient; administer doses >20mg/day qam or bid (am and noon)
Max: 80mg/day

Prozac Weekly:
Initiate 7 days after the last daily dose of 20mg cap
Consider reestablishing a daily dosing regimen if satisfactory response is not maintained

Switching to a TCA:
May need to reduce TCA dose and monitor plasma concentrations temporarily w/ coadministration or when fluoxetine has been recently discontinued

Obsessive Compulsive Disorder

Initial: 20mg/day qam
Titrate: Consider a dose increase after several weeks if improvement is insufficient; administer doses >20mg/day qam or bid (am and noon)
Range: 20-60mg/day
Max: 80mg/day

Bulimia Nervosa

Initial: 60mg/day qam; may titrate up to this target dose over several days
Max: 60mg/day

Panic Disorder

W/ or w/o Agoraphobia:
Initial: 10mg/day
Titrate: Increase to 20mg/day after 1 week; consider a dose increase after several weeks if no improvement
Max: 60mg/day

Bipolar I Disorder

Depressive Episodes:
In Combination w/ Olanzapine:
Initial: 20mg fluoxetine + 5mg olanzapine qpm
Range: 20-50mg fluoxetine + 5-12.5mg olanzapine
Max: 75mg fluoxetine + 18mg olanzapine

Major Depressive Disorder

Use in patients who do not respond to 2 separate trials of different antidepressants of adequate dose and duration in the current episode

In Combination w/ Olanzapine:
Initial: 20mg fluoxetine + 5mg olanzapine qpm
Range: 20-50mg fluoxetine + 5-20mg olanzapine
Max: 75mg fluoxetine + 18mg olanzapine

Dosing Considerations with MAOIs

Switching to/from an MAOI for Psychiatric Disorders:
Allow at least 14 days between discontinuation of an MAOI and initiation of treatment, and allow at least 5 weeks between discontinuation of treatment and initiation of an MAOI

W/ Other MAOIs (eg, Linezolid, IV Methylene Blue):
Do not start fluoxetine in patients being treated w/ linezolid or IV methylene blue
In patients already receiving fluoxetine, if acceptable alternatives are not available and benefits outweigh risks, d/c fluoxetine and administer linezolid or IV methylene blue; monitor for serotonin syndrome for 5 weeks or until 24 hrs after the last dose of linezolid or IV methylene blue, whichever comes 1st. May resume fluoxetine therapy 24 hrs after the last dose of linezolid or IV methylene blue

PEDIATRIC DOSAGE & INDICATIONS

Major Depressive Disorder

≥8 Years:
Initial: 10 or 20mg/day
Titrate: After 1 week at 10mg/day, increase to 20mg/day

Lower Weight Children:
Initial/Target: 10mg/day
Titrate: Consider a dose increase to 20mg/day after several weeks if improvement is insufficient

Switching to a TCA:
May need to reduce TCA dose and monitor plasma concentrations temporarily w/ coadministration or when fluoxetine has been recently discontinued

Obsessive Compulsive Disorder

≥7 Years:
Initial: 10mg/day
Titrate: Increase to 20mg/day after 2 weeks; consider additional dose increases after several more weeks if improvement is insufficient
Range: 20-60mg/day

Lower Weight Children:
Initial: 10mg/day
Titrate: Consider additional dose increases after several weeks if improvement is insufficient
Range: 20-30mg/day
Max: 60mg/day

Bipolar I Disorder

Depressive Episodes:
In Combination w/ Olanzapine:
10-17 Years:
Initial: 20mg fluoxetine + 2.5mg olanzapine qpm
Max: 50mg fluoxetine + 12mg olanzapine

Dosing Considerations with MAOIs

Switching to/from an MAOI for Psychiatric Disorders:
Allow at least 14 days between discontinuation of an MAOI and initiation of treatment, and allow at least 5 weeks between discontinuation of treatment and initiation of an MAOI

W/ Other MAOIs (eg, Linezolid, IV Methylene Blue):
Do not start fluoxetine in patients being treated w/ linezolid or IV methylene blue
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DOSING CONSIDERATIONS

Concomitant Medications
Combination w/ Olanzapine:
Patients Predisposed to Hypotensive Reactions w/ Hepatic Impairment, Slow Metabolizers, Pharmacodynamic Olanzapine Sensitivity:
Initial: 20mg fluoxetine + 2.5-5mg olanzapine
Titrate slowly and adjust dosage prn

Hepatic Impairment
Use lower or less frequent dosage

Elderly
Consider lower or less frequent dosage

Other Important Considerations

Concomitant Illness: May require dose adjustments

ADMINISTRATION

Oral route

Take w/ or w/o food

HOW SUPPLIED

Cap: 10mg, 20mg, 40mg; Cap, Delayed-Release (Prozac Weekly): 90mg

CONTRAINDICATIONS

Use of an MAOI for psychiatric disorders either concomitantly or within 5 weeks of stopping treatment. Treatment within 14 days of stopping an MAOI for psychiatric disorders. Starting treatment in patients being treated with other MAOIs (eg, linezolid, IV methylene blue). Concomitant use with pimozide or thioridazine.

WARNINGS/PRECAUTIONS

Serotonin syndrome reported; d/c immediately and initiate supportive symptomatic treatment. Anaphylactoid and pulmonary reactions reported; d/c if unexplained allergic reaction or rash occurs. May precipitate mixed/manic episode in patients at risk for bipolar disorder. Weight loss and anorexia reported. May increase risk of bleeding reactions. Pupillary dilation that occurs following use may trigger an angle-closure attack in a patient with anatomically narrow angles who does not have a patent iridectomy. Hyponatremia may occur; caution in elderly and volume-depleted patients. Consider discontinuation in patients with symptomatic hyponatremia and institute appropriate medical intervention. Convulsions, mania/hypomania, anxiety, insomnia, and nervousness reported. QT interval prolongation and ventricular arrhythmia (eg, torsades de pointes) reported. Caution in patients with congenital long QT syndrome, previous history of QT prolongation, family history of long QT syndrome or sudden cardiac death, and other conditions that predispose to QT prolongation and ventricular arrhythmia. Consider discontinuing treatment and obtaining cardiac evaluation if signs or symptoms of ventricular arrhythmia develop. Caution in patients with diseases/conditions that could affect hemodynamic responses or metabolism. May alter glycemic control in patients with diabetes. May impair mental/physical abilities. Long elimination $T_{1/2}$; changes in dose may not be fully reflected in plasma for several weeks. Adverse reactions reported upon discontinuation; avoid abrupt withdrawal.

ADVERSE REACTIONS

Somnolence, anorexia, anxiety, asthenia, diarrhea, dry mouth, dyspepsia, headache, insomnia, tremor, pharyngitis, flu syndrome, dizziness, nausea, nervousness.

DRUG INTERACTIONS

See Contraindications. Do not use thioridazine within 5 weeks of discontinuing therapy. Caution with CNS-active drugs. Avoid with other drugs that cause QT prolongation (eg, ziprasidone, erythromycin, quinidine). May cause serotonin syndrome with other serotonergic drugs (eg, triptans, TCAs, fentanyl) and with drugs that impair metabolism of serotonin; d/c immediately if this occurs. Increased risk of bleeding with aspirin, NSAIDs, warfarin, and other anticoagulants. Rare reports of prolonged seizures with electroconvulsive therapy. Drugs that are tightly bound to plasma proteins (eg, warfarin, digitoxin) may cause a shift in plasma concentrations, resulting in an adverse effect. Caution with CYP2D6 substrates, including antidepressants (eg, TCAs), antipsychotics (eg, phenothiazines and most atypicals), and antiarrhythmics (eg, propafenone, flecainide). Consider decreasing dose of drugs metabolized by CYP2D6, especially drugs with a narrow therapeutic index (eg, flecainide, propafenone, vinblastine). May prolong $T_{1/2}$ of diazepam. May increase levels of phenytoin, carbamazepine, haloperidol, clozapine, imipramine, and desipramine. Coadministration with alprazolam resulted in increased alprazolam levels and further psychomotor performance decrement. Anticonvulsant toxicity reported with phenytoin and carbamazepine. Antidiabetic drugs (eg, insulin, oral hypoglycemics) may require dose adjustment. May cause lithium toxicity; monitor lithium levels. Increased risk of hyponatremia with diuretics. Increased levels with CYP2D6 inhibitors.

PREGNANCY AND LACTATION

Category C, not for use in nursing.

MECHANISM OF ACTION

SSRI; has not been established. Presumed to be linked to its inhibition of CNS neuronal uptake of serotonin.

PHARMACOKINETICS

Absorption: (Single 40mg dose) C_{max}=15-55ng/mL, T_{max}=6-8 hrs. **Distribution:** Plasma protein binding (94.5%); crosses the placenta; found in breast milk. **Metabolism:** Liver (extensive) via CYP2D6; demethylation into norfluoxetine (active metabolite). **Elimination:** Kidney; $T_{1/2}$=1-3 days (acute administration), 4-6 days (chronic administration), 4-16 days (norfluoxetine, acute and chronic administration).

ASSESSMENT

Assess for volume depletion, history of seizures, risk for/presence of bipolar disorder, diseases/conditions that affect metabolism or hemodynamic responses, diabetes, susceptibility to angle-closure glaucoma, congenital long QT syndrome, previous history of QT prolongation, family history of long QT syndrome or sudden cardiac death, other conditions that predispose to QT prolongation and ventricular arrhythmia, pregnancy/nursing status, and possible drug interactions. Consider ECG assessment if initiating treatment in patients with risk factors for QT prolongation and ventricular arrhythmia.

MONITORING

Monitor for clinical worsening, suicidality, unusual changes in behavior, allergic reactions, serotonin syndrome, bleeding reactions, angle-closure glaucoma, altered appetite and weight, hyponatremia, seizures, activation of mania/hypomania, hypoglycemia/hyperglycemia, QT interval prolongation, ventricular arrhythmia, and other

adverse reactions. Monitor height and weight in children periodically. Consider periodic ECG monitoring if initiating treatment in patients with risk factors for QT prolongation and ventricular arrhythmia. Periodically reassess need for continued/maintenance treatment.

PATIENT COUNSELING

Inform of risks, benefits, and appropriate use of therapy. Counsel to be alert for the emergence of suicidality, unusual changes in behavior, or worsening of depression, especially early during treatment and when the dose is adjusted up or down. Inform about risk of serotonin syndrome with concomitant use with other serotonergic agents. Counsel to seek medical care immediately if rash/hives or unusual bruising/bleeding develops, or if experiencing signs/symptoms associated with serotonin syndrome or hyponatremia. Inform that drug may cause mild pupillary dilation, which in susceptible individuals, may lead to an episode of angle-closure glaucoma. Inform that QT interval prolongation and ventricular arrhythmia (eg, torsades de pointes) have been reported. Advise to avoid operating hazardous machinery or driving a car until effects of drug are known. Advise to inform physician if taking or planning to take any prescription or OTC drugs, if pregnant/intending to become pregnant, or if breastfeeding. Instruct to take ud, not to stop taking medication without consulting physician, and to consult physician if symptoms do not improve.

STORAGE

15-30°C (59-86°F). (Cap) Protect from light.

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