Dysphagia
Allergic Reactions and Rash

4.2 CONTRAINDICATIONS

Olanzapine and Fluoxetine Capsules (fluoxetine. Use with caution in conditions that predispose to arrhythmias or increased fluoxetine exposure. Use caution: Has been reported with antipsychotics, including Olanzapine and Fluoxetine.

Orthostatic Hypotension

Activation of Mania/Hypomania

5.4: Appropriate clinical monitoring is recommended, including fasting blood lipid testing before beginning.

Cerebrovascular Adverse Events (CVAE), Including Stroke - Cerebrovascular adverse events (e.g., stroke, transient ischemic attack), including fatalities, were reported in patients in trials of olanzapine in elderly patients with dementia-related psychosis. In placebo-controlled trials, there was a significantly higher incidence reported in patients in trials of olanzapine in elderly patients with dementia-related psychosis.

Consideration should be given to changing the therapeutic regimen, including possibly discontinuing the medication, in patients whose depression is persistently

Table 4

<table>
<thead>
<tr>
<th>Olanzapine 749</th>
<th>Wt gain mean (kg)</th>
<th>N (%)</th>
<th>Placebo - mean (kg)</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Olanzapine</td>
<td>6.5</td>
<td>4.6</td>
<td>Placebo</td>
<td>0.9</td>
</tr>
<tr>
<td>Fluoxetine</td>
<td>2.3</td>
<td>3.5</td>
<td></td>
<td></td>
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</tbody>
</table>

In an analysis of 7 controlled clinical studies, 2 of which were placebo-controlled, with treatment duration up to 12 weeks, olanzapine and fluoxetine-treated

The following symptoms, anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia (psychomotor restlessness),

In an analysis of 3 placebo-controlled olanzapine monotherapy studies of adolescent patients, including those with

In an analysis of 3 placebo-controlled olanzapine monotherapy studies of adolescent patients, including those with Schizophrenia (6 weeks) or Bipolar I Disorder (manic

Hyperprolactinemia may suppress hypothalamic GnRH, resulting in reduced pituitary gonadotropin secretion. This, in turn, may inhibit reproductive function by

In patients, both adult and pediatric, may experience worsening of their depression and/or the emergence of suicidal ideation, which is increased in patients with

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Adults: greater than or equal to 15% occurred in 14.1% of the olanzapine and fluoxetine group and none of the placebo group.

Commonly Observed Adverse Reactions in Controlled Studies Including Depressive Episodes Associated with Bipolar 1 Disorder — The most commonly observed adverse reactions reported in clinical trials of olanzapine and fluoxetine in combination are generally similar to those observed in clinical trials of olanzapine alone.

Musculoskeletal System

Back pain 2 1

General disorders and administration site reactions

Fluoxetine

General disorders and administration site reactions

Alopecia, dry skin, pruritis; exfoliative dermatitis.

Interactions (7.7)

Due to the large volume of distribution of olanzapine and fluoxetine, forced diuresis, dialysis, hemoperfusion, and exchange transfusion are unlikely to be of assistance. The clinical significance of concomitant use of olanzapine and fluoxetine with other drugs that may potentiate the orthostatic effect of olanzapine, e.g., diazepam or alcohol, should be considered.

Specific Precautions

A specific precaution involves patients who are taking or have recently taken olanzapine and fluoxetine and may have ingested excessive quantities of a TCA or monoamine oxidase inhibitor (MAOI). The combination of olanzapine and fluoxetine with TCAs, MAOIs, or other drugs that may potentiate the orthostatic effect of olanzapine should be avoided.

Drug Interactions

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Olanzapine and Fluoxetine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Taking into account the risk of metabolic changes, patients and caregivers should be counseled that metabolic changes have occurred during treatment with olanzapine and fluoxetine. Patients who have had previous metabolic changes and who are taking olanzapine and fluoxetine should be monitored regularly for worsening of glucose control or abnormal weight gain. Patients who have had recent metabolic changes should be monitored closely for changes in glucose control. If this occurs, the patient should be advised to seek medical attention immediately.

Patients should be advised of the potential risk of hyperglycemia-related adverse reactions. Patients should be monitored regularly for worsening of glucose control.

Patients should be advised of the risk of orthostatic hypotension, especially during the period of initial dose titration and in association with the use of concomitant drugs that may potentiate the orthostatic effect of olanzapine, e.g., diazepam or alcohol.

Patients should be advised of the risk of chest pain, dyspnea, heart murmurs, symptoms of pheochromocytoma (e.g., headache, sweating, palpitations, anxiety, flushing, nausea, and vomiting), and symptoms of upper respiratory tract infections (e.g., sore throat, rhinorrhea, cough, or fever) associated with amiodarone, sotalol; and others (e.g., pentamidine, levomethadyl acetate, methadone, halofantrine, mefloquine, dolasetron mesylate, probucol or tacrolimus).

There are no clinical studies establishing the benefit of the combined use of ECT and fluoxetine. There have been rare reports of prolonged seizures in patients who were receiving olanzapine and fluoxetine and also receiving ECT.

The safety and effectiveness of olanzapine and fluoxetine in combination for treatment resistant depression in patients under 18 years of age have not been established. The safety and effectiveness of olanzapine and fluoxetine in combination for the treatment of acute mania in patients under 18 years of age have not been established. The safety and effectiveness of olanzapine and fluoxetine in combination for the treatment of schizophrenia in patients under 18 years of age have not been established.

The safety and effectiveness of olanzapine and fluoxetine in combination for the treatment of bipolar disorder in patients under 18 years of age have not been established.

There is something you do not understand or you want to learn more about olanzapine and fluoxetine capsules.

What else do I need to know about antidepressant medicines?

What are the ingredients in Olanzapine and Fluoxetine Capsules? The ingredients include:

- D&C yellow No. 10, ethanol, FD&C blue No. 1, FD&C blue No. 2, FD&C red No. 40, iron oxide black, methanol, n-Butyl alcohol, propylene glycol,