WARNINGS AND PRECAUTIONS

Neuroleptic Malignant Syndrome (NMS):
Revised: 02/2013

Other Contraindications:

Specific Populations:

Allergic Reactions and Rash

Hyperlipidemia

Clinical Worsening and Suicide Risk

Leukopenia, Neutropenia, and Agranulocytosis

Orthostatic Hypotension

Uncommon adverse reactions that may occur include serotonin syndrome, which can be serious, with symptoms such as severe confusion, agitation, and tremor. Symptoms may occur with the initiation or dose increase of olanzapine and fluoxetine capsules. Serotonin syndrome may occur in patients taking serotonin-containing medications (e.g., fentanyl, lithium, tramadol, tryptophan, buspirone, and St. John's Wort) and with drugs that impair metabolism of serotonin (in particular, aminoglycosides, atypical antipsychotics, linezolid, maprotiline, melatonin, milnacipran, more than one monoamine oxidase inhibitor, phenelzine, tramadol, tryptophan, and tryptophan-containing foods) and with drugs that are associated with a CYP2D6 inhibition mechanism (in particular, paroxetine and quinidine).

Serotonin syndrome potentially occurs with the use of olanzapine and fluoxetine capsules and other medications associated with the potential for serotonergic interaction. It is important to monitor patients taking olanzapine and fluoxetine capsules for the emergence of symptoms of serotonin syndrome, which include hyperthermia, tremor, shivering, myoclonus, agitation, confusion, diarrhea, and hyperreflexia. Particular caution is warranted in patients taking serotonergic antidepressants (e.g., selective serotonin reuptake inhibitors, serotonin norepinephrine reuptake inhibitors), monoamine oxidase inhibitors, or other drugs and chemicals that may interact with serotonin levels.

The potential for a serotonin syndrome with olanzapine and fluoxetine capsules was evaluated in short-term placebo-controlled clinical studies of adult outpatients and in a limited number of long-term studies in patients with schizophrenia. In these studies, the serotonin syndrome did not occur in the absence of concomitant agents associated with the potential for a serotonin syndrome. However, because of the potential for a serious interaction, it is important to monitor patients taking olanzapine and fluoxetine capsules for the emergence of symptoms of serotonin syndrome, which include hyperthermia, tremor, shivering, myoclonus, agitation, confusion, diarrhea, and hyperreflexia. Particular caution is warranted in patients taking serotonergic antidepressants (e.g., selective serotonin reuptake inhibitors, serotonin norepinephrine reuptake inhibitors), monoamine oxidase inhibitors, or other drugs and chemicals that may interact with serotonin levels.

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