**DOSAGE FORMS AND STRENGTHS**

RELEASE TABLETS safely and effectively. See full prescribing information for QUETIAPINE FUMARATE.
Laboratory, ECG and vital sign changes observed in clinical studies

The following findings were based on a 3-week placebo-controlled trial in which quetiapine was administered in either a 200 mg or 400 mg group. In the 400 mg group, dizziness (8% vs. 15%), dry mouth (4% vs. 10%), and tachycardia (6% vs. 11%) were observed.

The adverse reactions leading to discontinuation in 2% or more of patients was 11.4% and 4.4%, respectively. The adverse reactions leading to discontinuation in 2% or more of patients were:

- Fatigue
- Anorexia
- Weight increased
- Vomiting
- Dizziness
- Insomnia
- Nasal congestion
- Sialorrhea
- Nausea

In Tables 22 and 23, dystonic events included nuchal rigidity, hypertonia, dystonia, and muscle rigidity; parkinsonism was observed in 2% or more of patients.

The efficacy of quetiapine fumarate extended-release tablets in the acute treatment of manic episodes was established in one 8-week, double-blind, placebo-controlled, multicenter trial. Patients who met DSM-IV diagnostic criteria for a manic episode were included in the study. The primary endpoint in these studies was time to relapse.

Table 21 enumerates the incidence, rounded to the nearest percent, of treatment-emergent adverse reactions that were at least as common among patients treated with quetiapine as placebo, or were statistically significantly increased over placebo.

Table 22 presents a listing of patients with adverse reactions associated with EPS in a short-term placebo-controlled trial in which quetiapine was administered in either a 200 mg or 400 mg group. The following findings were based on a 3-week placebo-controlled trial in which quetiapine was administered in either a 200 mg or 400 mg group.

Table 23 below presents a listing of patients with adverse reactions associated with EPS in a short-term placebo-controlled trial in which quetiapine was administered in either a 200 mg or 400 mg group.

The potential effects of several concomitant medications on quetiapine pharmacokinetics were studied. There are no clinically relevant pharmacokinetic interactions of quetiapine fumarate tablets on other drugs based on CYP3A4 enzyme inhibition data. Quetiapine fumarate extended-release tablets and placebo in decreasing depression symptoms in children and adolescents with 8.2 Labor and Delivery.

8.1 Pregnancy

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