

Commonly Observed Adverse Reactions in Short-Term, Placebo-Controlled Trials:

In an acute (8-week) quetiapine fumarate extended-release tablet trial in children and adolescents (10 to 17 years of age) with bipolar depression, the most commonly observed adverse reactions associated with the use of quetiapine fumarate extended-release tablets (incidence of 5% or greater and at least twice that for placebo) were: dizziness 7%, diarrhea 5%, fatigue 5%, and nausea 5%.

In therapy for schizophrenia (up to 6 weeks), the most commonly observed adverse reactions associated with the use of quetiapine in adolescents (incidence of 5% or greater and quetiapine incidence at least twice that for placebo) were somnolence (34%), dizziness (12%), dry mouth (7%), tachycardia (7%), and weight increase (7%).

In bipolar mania trials (up to 3 weeks), the most commonly observed adverse reactions associated with the use of quetiapine in children and adolescents (incidence of 5% or greater and quetiapine incidence at least twice that for placebo) were somnolence (53%), dizziness (19%), fatigue (14%), increased appetite (5%), nausea (5%), vomiting (8%), tachycardia (7%), dry mouth (7%), and weight increase (15%).

Adverse Reactions Occurring at an Incidence of 22% Among Immediate Release Quetiapine Fumarate Tablets Treated Patients in Short-Term, Placebo-Controlled Trials in Children and Adolescents

The following findings were based on a 6-week placebo-controlled trial in which quetiapine was administered in either doses of 400 mg or 600 mg.

Table 20 summarizes the incidence, rounded to the nearest percent, of adverse reactions that occurred during therapy (up to 6 weeks) of schizophrenia in 2% or more of patients treated with immediate release quetiapine fumarate tablets (doses of 400 or 600 mg) when the incidence in patients treated with immediate release quetiapine fumarate tablets was greater than the incidence in placebo-treated patients.

Adverse reactions that were potentially dose-related with higher frequency in the 800 mg group compared to the 400 mg group included dizziness (15% vs 12%), dry mouth (4% vs 1%), and tachycardia (6% vs 1%).

Table 20. Adverse Reactions in a 6-Week Placebo-Controlled Clinical Trial for the Treatment of Schizophrenia in Adolescent Patients

Preferred Term	Immediate Release Quetiapine Fumarate Tablets 400 mg (n=73)	Immediate Release Quetiapine Fumarate Tablets 800 mg (n=74)	Placebo (n=75)
Somnolence	32%	35%	11%
Dizziness	12%	15%	5%
Dry Mouth	7%	10%	1%
Tachycardia	7%	1%	1%
Insomnia	3%	5%	0%
Anorexia	1%	3%	0%
Back Pain	1%	3%	0%
Abdominal Pain	3%	1%	0%
Anorexia	3%	1%	0%
Headache	3%	1%	0%
Dyskinesia	3%	0%	0%
Weight Increase	15%	15%	7%
Weight Decrease	3%	0%	0%

¹ Somnolence combines adverse reaction terms somnolence and sedation.

² Tachycardia combines adverse reaction terms tachycardia and sinus tachycardia.

Bipolar I Mania (Children and Adolescents 10 to 17 years old)

The following findings were based on a 3-week placebo-controlled trial in which quetiapine was administered in either doses of 400 or 600 mg.

Table 21 summarizes the incidence, rounded to the nearest percent, of treatment-emergent adverse reactions that occurred during therapy (up to 3 weeks) of bipolar mania in 2% or more of patients treated with immediate release quetiapine fumarate tablets (doses of 400 or 600 mg) when the incidence in patients treated with immediate release quetiapine fumarate tablets was greater than the incidence in placebo-treated patients.

Adverse reactions that were potentially dose-related with higher frequency in the 800 mg group compared to the 400 mg group included somnolence (50% vs 37%), nausea (16% vs 9%), and tachycardia (6% vs 3%).

Table 21. Adverse Reactions in a 3-Week Placebo-Controlled Clinical Trial for the Treatment of Bipolar Mania in Children and Adolescents

Preferred Term	Immediate Release Quetiapine Fumarate Tablets 400 mg (n=55)	Immediate Release Quetiapine Fumarate Tablets 800 mg (n=56)	Placebo (n=56)
Somnolence	50%	37%	14%
Dizziness	19%	17%	4%
Nausea	16%	9%	4%
Headache	10%	10%	4%
Increased Appetite	10%	10%	4%
Weight Increase	10%	10%	4%
Weight Decrease	7%	7%	4%
Vomiting	7%	7%	4%
Nasal Congestion	6%	6%	4%
Diarrhea	6%	6%	4%
Weight Increase	6%	6%	4%
Weight Decrease	6%	6%	4%
Aggression	4%	4%	2%
Musculoskeletal Stiffness	4%	4%	2%
Accidental Overdose	4%	4%	2%
Aggression	4%	4%	2%
Weight Increase	4%	4%	2%
Weight Decrease	4%	4%	2%
Aggression	4%	4%	2%
Weight Increase	4%	4%	2%
Weight Decrease	4%	4%	2%
Aggression	4%	4%	2%
Weight Increase	4%	4%	2%
Weight Decrease	4%	4%	2%
Aggression	4%	4%	2%
Weight Increase	4%	4%	2%
Weight Decrease	4%	4%	2%

¹ Somnolence combines adverse reaction terms somnolence and sedation.

² Tachycardia combines adverse reaction terms tachycardia and sinus tachycardia.

Etiopathogenic Mechanisms

Safety and effectiveness of quetiapine fumarate extended-release tablets is supported by studies of immediate release quetiapine fumarate tablets in children and adolescent patients 10 to 17 years of age (see Clinical Studies (14.1 and 14.2)).

In short-term placebo-controlled trials, the incidence of adverse reactions in children and adolescent patients (10 to 17 years of age) with bipolar depression (8-week duration), in which efficacy was not established, the aggregated incidence of extrapyramidal symptoms was 1% (15/2) for quetiapine fumarate extended-release tablets and 0% (0/10) for placebo.

In short-term placebo-controlled trials, the incidence of adverse reactions in children and adolescent patients (13 to 17 years of age) with schizophrenia (6-week duration), the aggregated incidence of extrapyramidal symptoms was 12.9% (19/147) for immediate release quetiapine fumarate tablets and 3.2% (10/312) for placebo.

In Table 22 and 23, dystonic events included nuchal rigidity, dyskinesia, dystonia, and muscle rigidity; parkinsonism included cogwheel rigidity and tremor; akathisia included akathisia only; dystonic event included acute dystonia, dyskinesia and choreoathetosis; and other extrapyramidal event included orofacial dyskinesia.

Table 22 below presents a listing of patients with adverse reactions associated with EPS in a short-term placebo-controlled immediate release quetiapine fumarate monotherapy trial in adolescent patients with schizophrenia (6-week duration).

Table 22. Adverse Reactions Associated with Extrapyramidal Symptoms in the Placebo-Controlled Trial

Preferred Term	Immediate Release Quetiapine Fumarate Tablets 400 mg (n=73)	Immediate Release Quetiapine Fumarate Tablets 800 mg (n=74)	All Immediate Release Quetiapine Fumarate Tablets (n=147)	Placebo (n=75)
Dystonic event	0	0	0	0
Parkinsonism	4	5	9	2
Akathisia	3	4	7	4
Other extrapyramidal event	2	2	4	0

Table 23 below presents a listing of patients with adverse reactions associated with EPS in a short-term placebo-controlled monotherapy trial in children and adolescent patients with bipolar mania (3-week duration).

Table 23. Adverse Reactions Associated with Extrapyramidal Symptoms in a Placebo-Controlled Trial in Children and Adolescent Patients with Bipolar Mania (3-week duration)

Preferred Term	Immediate Release Quetiapine Fumarate Tablets 400 mg (n=55)	Immediate Release Quetiapine Fumarate Tablets 800 mg (n=56)	All Immediate Release Quetiapine Fumarate Tablets (n=111)	Placebo (n=56)
Parkinsonism	0	2	2	1
Akathisia	1	0	1	0
Other extrapyramidal event	1	0	1	0

There were no adverse reactions with the preferred terms of dystonia or dyskinesias.

Laboratory, ECG and vital sign changes observed in clinical studies

Laboratory Changes:

In three-arm quetiapine fumarate extended-release tablets placebo-controlled monotherapy clinical trials, among patients with a baseline neutrophil count $\geq 1.5 \times 10^9$ /mm³, the incidence of at least one occurrence of neutrophil count $< 1.5 \times 10^9$ /mm³ was 1.2% in patients treated with quetiapine fumarate extended-release tablets and 1.5% for immediate release quetiapine fumarate tablets, compared to 0.8% for placebo-treated patients.

In placebo-controlled monotherapy clinical trials involving 3362 patients on quetiapine fumarate and 1515 on placebo, the incidence of at least one occurrence of neutrophil count $< 1.0 \times 10^9$ /mm³, among patients with a normal baseline neutrophil count and at least one available follow-up laboratory measurement was 1.3% (10/745) for quetiapine fumarate extended-release tablets, compared to 0.1% (2/1343) in patients treated with placebo (see Warnings and Precautions (5.7)).

Transaminase Elevations:

Adults: Asymptomatic, transient and reversible elevations in serum transaminase (primarily ALT) have been reported. The proportions of adult patients with transaminase elevations of ≥ 3 times the upper limit of normal reference range in a pool of placebo-controlled trials ranged between 1% and 2% for quetiapine fumarate tablets compared to 2% for placebo. In schizophrenia trials, in children and adolescents, the proportions of patients with transaminase elevations of ≥ 3 times the upper limit of the normal reference range in a pool of placebo-controlled trials were approximately 5% for immediate release quetiapine fumarate tablets and 1.5% for placebo (see Warnings and Precautions (5.7)).

In placebo-controlled trials, the proportions of patients with transaminase elevations of ≥ 3 times the upper limit of normal reference range in a pool of placebo-controlled trials were approximately 5% for immediate release quetiapine fumarate tablets and 1.5% for placebo (see Warnings and Precautions (5.7)).

There have been literature reports suggesting false positive results in urine enzyme immunoassays for methadone and tricyclic antidepressants in patients who have taken quetiapine. Caution should be exercised in the interpretation of positive urine drug screen results and confirmatory by alternative analytical technique (e.g., chromatographic methods) should be considered.

ECG Changes:

Adults: 25% of quetiapine fumarate extended-release tablet patients, and 23% of placebo patients, had tachycardia (>100 bpm) at one or more time points. The proportions of patients with tachycardia were 15% for quetiapine fumarate extended-release tablets and 12% for placebo.

In a 6-week (8-week) quetiapine fumarate extended-release tablets trial in children and adolescents (10 to 17 years of age), increases in heart rate (>10 bpm) occurred in 1.1% of patients receiving immediate release quetiapine fumarate tablets 400 mg and 4.7% of patients receiving immediate release quetiapine fumarate tablets 800 mg compared to 0% of patients receiving placebo. Mean increases in heart rate were 3.8 bpm and 11.2 bpm for immediate release quetiapine fumarate tablets 400 mg and 800 mg, respectively, compared to a decrease of 3.3 bpm in the placebo group (see Warnings and Precautions (5.7)).

6.2 Post-Marketing Experience

The following adverse reactions were identified during post approval use of immediate release quetiapine fumarate tablets. Because these adverse reactions are reported variably from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Adverse reactions reported since market introduction which were temporally related to quetiapine therapy include anaphylactic reaction, cardiomyopathy, drug reaction with eosinophilia and systemic symptoms (DRESS), hyponatremia, myoclonus, nocturnal enuresis, neuroleptic malignant syndrome, neuroleptic malignant syndrome (NMS), Stevens-Johnson syndrome, and toxic epidermal necrolysis (TEN).

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