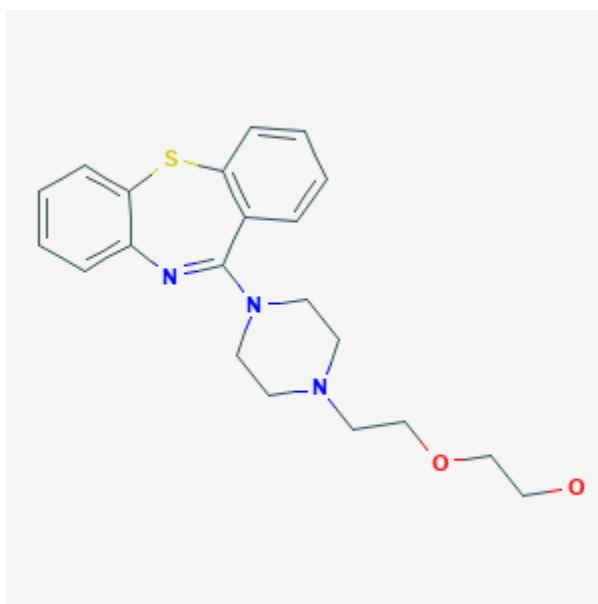




## Quetiapine

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CASRN: 111974-69-7



## Drug Levels and Effects

### Summary of Use during Lactation

Maternal quetiapine doses of up to 400 mg daily produce low levels in milk. Limited long-term follow-up of infants exposed to quetiapine indicates that infants generally developed normally. Systematic reviews of second-generation antipsychotics concluded that quetiapine seemed to be the first- or second-choice agent during breastfeeding.[1][2] Monitor the infant for drowsiness and developmental milestones, especially if other antipsychotics are used concurrently.

### Drug Levels

*Maternal Levels.* One mother took oral quetiapine 200 mg daily throughout pregnancy and postpartum. At 3 weeks postpartum, milk samples were taken. The average milk level over the 6-hour dosage interval was 13 mcg/L. A peak milk quetiapine level of 62 mcg/L occurred at 1 hour after the dose. The authors estimated that

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an exclusively breastfed infant would receive 0.09% of the weight-adjusted maternal dosage on average, with a "worst-case" dosage (assuming all nursing was at the peak concentration) of 0.43% of weight-adjusted maternal dosage.[3]

Six nursing mothers who were 6.5 to 18.5 weeks postpartum were taking quetiapine in doses of 25 to 400 mg daily in addition to an antidepressant for major depression postpartum. Milk samples obtained at various times after the dose had undetectable (<11.5 mcg/L) levels of quetiapine in the 4 mothers taking 75 mg daily or less. A mother taking 100 mg daily had a milk quetiapine level of 12.3 mcg/L and another taking 400 mg daily had a level of 101 mcg/L. The authors estimated that exclusively breastfed infants would receive less than 0.01 mg/kg daily with maternal doses of 100 mg daily or less and less than 0.1 mg/kg daily with a maternal dose of 400 mg daily.[4]

A woman who was 3 months postpartum and taking quetiapine 400 mg daily, fluoxetine 40 mg daily, and oxycodone 20 mg 3 times daily had 16 milk samples taken over 24 hours starting immediately before a daily dose of quetiapine; 12 were paired fore- and hindmilk and the other 4 samples were mixtures of fore- and hindmilk. The highest quetiapine level measured in milk of about 170 mcg/L occurred within 1 hour after the dose. Milk levels dropped to nearly zero by 12 hours after the dose. No differences were noted between fore- and hindmilk concentrations. The authors estimated that the infant received 6.2 mcg/kg daily and that a fully breastfed infant would receive 0.09% of the maternal weight-adjusted dosage.[5]

A nursing mother was taking quetiapine in a dosage of 200 mg daily. Quetiapine was undetectable (<5 mcg/L) in her breastmilk.[6]

In a study of 9 women taking quetiapine in an average dose of 37 mg daily (range 6.25 - 100 mg daily), simulations of infant exposure indicated that the infant would receive <0.5% of the maternal weight-adjusted dosage.[7] Further analysis of the data was performed using NONMEM. Using the data obtained, 1000 computer simulations of breastmilk concentrations and infant dosages were performed. Results showed that 99% of breastfed infants would ingest quetiapine in dosages below 0.42% of the maternal weight-adjusted dose.[8]

One woman was taking quetiapine 200 mg daily at 11 pm. She avoided breastfeeding from 11 pm to 7 am each day. Breastmilk samples were collected at 4 am, 8 am and 11 pm daily for 26 days. The average quetiapine concentrations in her breastmilk were 11.7 mcg/L, at 4 am, 5.4 mcg/L at 8 am, and 0.9 mcg/L at 11 pm. The authors estimated that her infant would receive a maximum of 0.37 mg/kg daily and a median dosage of 0.1 mg/kg daily, which would translate to 0.017% and 0.005% of the weight-adjusted maternal dosage, respectively. [9]

A woman with bipolar disorder who delivered twins and was taking sodium valproate was started on quetiapine 200 mg and olanzapine 15 mg at 11 pm daily after 20 days postpartum. She withheld breastfeeding during the night and discarded milk pumped at 7 am. She then breastfed her infants until 11 pm. After 7 days of therapy, milk samples were obtained at 4 am, 8 am and 11 pm for 27 of the next 45 days. The median average daily quetiapine milk concentration was 3.7 mcg/L. Median milk concentrations were 10.7 mcg/L at 4 am, 3.7 mg/L at 8 am and 0.9 mg/L at 11 pm. The authors calculated that if the infants had been fully breastfed, they would have received a daily dosage of 0.38 mcg/kg or 0.02% of the maternal weight-adjusted dosage. By withholding nursing during the night, the infants' quetiapine dosage was reduced by 55% compared to the dose they would have received if they had been breastfed around the clock.[10]

Nine breastfeeding mothers who were taking rapid-release quetiapine in an average dose of 41 mg daily provided milk samples at approximately 0, 1, 2, 4, 7, 12, and 24 hours after a dose. The peak milk concentration of quetiapine occurred at 2 hours after the dose and declined with a half-life of 7.4 hours. The average milk concentration was 5.7 mcg/L (range 1.4 to 13.9 mcg/L). The authors estimated the mean infant quetiapine dose was 0.16% of the maternal weight-adjusted dosage.[11]

*Infant Levels.* A 3-month-old infant who was breastfed 6 to 7 times daily during maternal use of 400 mg daily of quetiapine had a plasma quetiapine level of 1.4 mcg/L. This level was 6% of the mother's quetiapine plasma level at the same time.[5]

In a study of 9 women taking quetiapine in an average dose of 37 mg daily (range 6.25 - 100 mg daily), simulations of infant exposure indicated that the infant would be expected to attain serum concentrations <0.6% of the maternal serum quetiapine concentration.[7]

A woman was taking quetiapine 100 mg each night for treatment of bipolar disorder during 2 pregnancies. and during breastfeeding. She breastfed both preterm infants and on 2 days, milk was pumped 1 hour after the dose, at the presumed time of the peak milk quetiapine level and given to the infant. Infant serum levels were measured one hour after the breastmilk intake on 2 separate occasions. In one infant, serum quetiapine levels were <1 and 3 mcg/L on days 6 and 33 of age, respectively. In the second infant, serum quetiapine levels were 0 (<0.096 mcg/L) and 15 mcg/L on days 4 and 6 of age, respectively.[12]

## Effects in Breastfed Infants

One mother took quetiapine 25 mg daily orally during pregnancy and continued to take quetiapine 50 mg daily orally during lactation. At 6 weeks the infant was doing well. No further follow-up was reported.[13]

Another infant whose mother was taking 200 mg daily of quetiapine began to exclusively breastfeed at 8 weeks of age. The infant was developing well at 4.5 months of age and no adverse effects were reported.[3]

A nursing mother with postpartum psychosis was started on quetiapine at 6 weeks postpartum at a dose of 25 mg daily along with unspecified benzodiazepines. The quetiapine dosage was increased gradually to 200 mg daily over the next 6 weeks and up to 300 mg daily over the ensuing 4 weeks (16 weeks postpartum). She was also started on mirtazapine 15 mg daily at 8 weeks postpartum. Breastfeeding (extent not specified) was continued until 16 weeks postpartum when it was stopped because of reduced milk production. During this time the infant was excessively drowsy until the benzodiazepine dosage was decreased at the same time as the quetiapine dosage was increased. The infant was followed for at least 2 months after breastfeeding ended and no effects on the infant's growth, motor or psychological development or signs of infant withdrawal were noted.[14]

A nursing mother with bipolar disorder began taking 20 mg of paroxetine at 4 months postpartum and was then started on quetiapine 200 mg twice daily at 6 months postpartum. She breastfed regularly (extent not stated) and no obvious adverse effects were noted in the infant.[15]

A woman who was treated chronically with quetiapine 400 mg and fluvoxamine 200 mg daily took the drugs throughout pregnancy and postpartum. She partially breastfed her infant (extent not stated) for 3 months from birth. No adverse events were seen and the infant developed normally.[16]

Six nursing mothers took quetiapine in doses of 25 to 400 mg daily in addition to an antidepressant (usually paroxetine) for major depression postpartum. Their breastfed infants' development were tested at 9 to 18 months of age with the Bayley scales. Measurements were slightly low on the mental and psychomotor development scale in one infant and on the mental development scale in another. All other scores were within normal limits. The authors concluded that the low scores of the 2 infants were probably not caused by the drugs received by the infants in breastmilk.[4]

An infant was born to a mother taking quetiapine 400 mg daily, fluoxetine 40 mg daily and oxycodone 20 mg 3 times daily. The infant was breastfed 6 to 7 times daily and was receiving 120 mcg of oral morphine 3 times daily for opiate withdrawal. Upon examination at 3 months of age, the infant's weight was at the 25th percentile for age, having been at the 50th percentile at birth. The authors attributed the weight loss to opiate withdrawal. The infant's Denver developmental score was equal to his chronological age.[5]

One 60-week-old infant who was 50% breastfed was breastfed during maternal therapy with quetiapine 75 mg daily and venlafaxine 225 mg daily. No adverse reactions were reported by the mother or in the medical records.[17]

A woman with bipolar disorder who delivered twins and was taking sodium valproate in a therapeutic dosage was started on quetiapine 200 mg and olanzapine 15 mg at 11 pm daily after 20 days postpartum. She withheld breastfeeding during the night and discarded milk pumped at 7 am. She then breastfed her infants until 11 pm. The mother continued feeding the infants on this schedule for 15 months. Monthly follow-up of the infants indicated normal growth and neither the pediatricians nor the parents noted any adverse effects in the infants. [10]

A mother taking quetiapine 100 mg each night for bipolar disorder breastfed 2 successive preterm infants. Both infants were reported to be developing normally at their last follow-up visits (exact times not specified).[12]

A woman with bipolar disorder took quetiapine 25 mg and lamotrigine 100 mg daily for the treatment of bipolar disorder during two pregnancies. After the first birth, she did not breastfeed, but she breastfed (extent not stated) the second infant. At the 2-month well baby checkup, the infant was meeting all developmental milestones.[18]

A woman received a combination of 300 mg lamotrigine and 300 of quetiapine daily for postpartum bipolar II postpartum depression. The authors reported no major adverse reactions in her breastfed (extent not stated) infant.[19]

An author reported 1 infant who was breastfed (extent not stated) during postpartum maternal treatment for bipolar disorder. Her quetiapine dosage was 200 mg daily. The mother reported no adverse effects in the infants. [20]

## Effects on Lactation and Breastmilk

Unlike the phenothiazines, quetiapine has a minimal effect on serum prolactin levels.[21][22][23]

Galactorrhea occurred in a woman who was not breastfeeding while she was taking venlafaxine 112.5 mg daily and quetiapine. Galactorrhea occurred 10 days after her quetiapine dose was increased to 50 mg daily a few days after starting the drug at 12.5 mg daily. Her serum prolactin level was 27.3 mcg/L (normal 2 to 30 mcg/L) and decreased to 8.5 mcg/L 2 weeks after discontinuing the drug. Galactorrhea ceased 1 week later.[24]

The maternal prolactin level in a mother with established lactation may not affect her ability to breastfeed.

## Alternate Drugs to Consider

Haloperidol, Olanzapine, Risperidone

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## Substance Identification

### Substance Name

Quetiapine

## CAS Registry Number

111974-69-7

## Drug Class

Breast Feeding

Lactation

Antipsychotic Agents