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Fluoxetine

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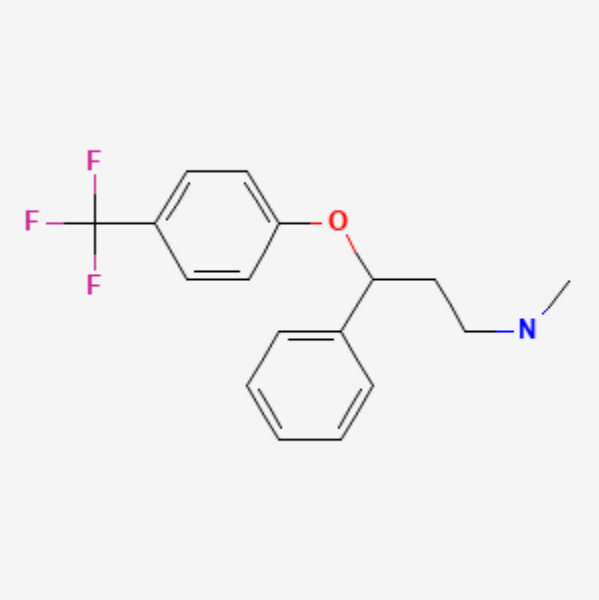

Drug Levels and Effects

Summary of Use during Lactation

The average amount of drug in breastmilk is higher with fluoxetine than with most other SSRIs and the long-acting, active metabolite, norfluoxetine, is detectable in the serum of most breastfed infants during the first 2 months postpartum and in a few thereafter. Adverse effects such as colic, fussiness, and drowsiness have been reported in some breastfed infants. Decreased infant weight gain was found in one study, but not in others. No adverse effects on development have been found in infants followed for up to 5 years of age.

If fluoxetine is required by the mother, it is not a reason to discontinue breastfeeding. A safety scoring system finds fluoxetine use to be possible during breastfeeding,[1] although others do not recommend its use.[2] If the mother was taking fluoxetine during pregnancy or if other antidepressants have been ineffective, most experts

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recommend against changing medications during breastfeeding. Otherwise, agents with lower excretion into breastmilk may be preferred, especially while nursing a newborn or preterm infant. The breastfed infant should be monitored for behavioral side effects such as colic, agitation, irritability, poor feeding, and poor weight gain.

Mothers taking an SSRI during pregnancy and postpartum may have more difficulty breastfeeding, although this might be a reflection of their disease state.[3] These mothers may need additional breastfeeding support. Breastfed infants exposed to an SSRI during the third trimester of pregnancy are at risk for neonatal withdrawal syndrome consisting of hypoglycemia, tremors, tachycardia, or hypotonia, and might be at a greater risk of readmission due to jaundice.[4,5]

Drug Levels

Fluoxetine is metabolized to norfluoxetine which has antidepressant activity that is considered to be equal to fluoxetine.[2]

Maternal Levels. In a pooled analysis of serum levels from published studies and 1 unpublished case, the authors found that 20 mothers taking an average daily dosage of 28 mg (range 10 to 80 mg) had an average milk fluoxetine level of 76 mcg/L (range 23 to 189 mcg/L).[6] Using the average dosage and milk level data from this paper, an exclusively breastfed infant would receive an estimated 2.4% of the maternal weight-adjusted dosage of fluoxetine; however, the substantial contribution of norfluoxetine was not considered. In one of the studies included in the pooled analysis that measured both fluoxetine and norfluoxetine in 14 mothers, the average daily infant dosage in breastmilk was about 7% (range 3 to 12%) of the mother's weight-adjusted dosage.[6]

Eleven women taking fluoxetine 20 to 40 mg daily during pregnancy and lactation had trough milk fluoxetine and norfluoxetine levels measured on day 4, week 2 and month 2 postpartum. When standardized to a 20 mg daily dosage, total drug concentration in breastmilk ranged from 75.4 to 91.5 mcg/L at the 3 times. The authors estimated that an exclusively breastfed infant would receive a minimum of 2.4% and 3.8% of the maternal weight-adjusted dosage of the drug and metabolite combined with this maternal dosage regimen at 2 weeks and 2 months of age, respectively.[7]

In 1 mother who was 11 weeks postpartum and taking fluoxetine in a daily dosage of 20 mg, the authors estimated that an exclusively breastfed infant would receive 3.3% of the maternal weight-adjusted dosage.[8]

At 2 months postpartum, 7 mothers taking an average of 24 mg of fluoxetine daily had average breastmilk levels of 63.7 mcg/L of fluoxetine and 103.8 mcg/L of norfluoxetine. These data indicate that a fully breastfed infant would receive 25 mcg/kg daily of fluoxetine plus norfluoxetine. This value would be about 6.3% of the maternal weight-adjusted dosage.[9]

Twenty-three nursing mothers who were taking fluoxetine in an average dose of 21 mg daily for a minimum of 4 weeks and averaging 3.7 months postpartum had random foremilk samples (n = 30) analyzed for *R*- and *S*-isomers of fluoxetine and norfluoxetine. The weight-adjusted dosages of these infants (average 91% breastfed) were calculated to be 0.54% and 0.57% of the maternal weight-adjusted dosage for fluoxetine and norfluoxetine, respectively. The concentrations of the active *S*-isomer in milk were about 1.9 times that of the *R*- isomer.[10]

Data from 24 women on the excretion of fluoxetine and norfluoxetine into milk from two previously published studies[11,12] were combined and reanalyzed using NONMEM. Data from the two original papers were previously included in a pooled analysis reported above.[6] Simulations of the data indicated that a fully breastfed infant would receive a median of 0.017 mg/kg daily of fluoxetine plus norfluoxetine. This resulted in a median weight-adjusted percentage of 5.9% of the maternal dosage, with a 99th percentile value of 23%.[13]

Four women taking fluoxetine 20 mg daily had an average breastmilk fluoxetine concentration of 51 mcg/L at times that were not stated. These values equated to an average infant dosage of 7.6 mcg/kg daily or 2.2% of the maternal weight-adjusted dosage.[14]

A nursing mother was taking fluoxetine 20 mg daily. Foremilk and hindmilk samples taken at 1 week postpartum, 2 hours after a dose contained 19 mcg/L and 16 mcg/L, respectively. The samples also contained 36 mcg/L and 30 mcg/L of norfluoxetine in foremilk and hindmilk, respectively.[15]

A mother taking 40 mg of fluoxetine daily since conception donated one mature breastmilk sample 4 hours after a dose. Fluoxetine concentration was 98.2 mcg/L and norfluoxetine was 56.3 mcg/L. In 17 women who received a single 20 mg dose of fluoxetine prepartum, colostrum samples taken 23 to 54 hours postpartum. Fluoxetine was found in 3 samples below the quantification level of 3 mcg/L and above the level of detection of 1 mcg/L; in all other samples fluoxetine was below the level of detection. Norfluoxetine was found in all the samples, but below the level of quantification of 4 mcg/L.[16]

Two women treated with fluoxetine 20 mg daily during the third trimester of pregnancy and during breastfeeding provided trough milk samples during the first week postpartum. Fluoxetine milk levels were 142.9 and 216.8 mcg/L, with calculated weight-adjusted percentage of maternal dosages 13.1% and 20%, respectively. These values might be inaccurate because of the timing of milk sample collection and the failure to quantitate norfluoxetine.[17]

Infant Levels. In a pooled analysis of 22 mother-infant pairs from published and unpublished cases, the authors found that infants had an average of 7% (range 0 to 59%) of their mothers' fluoxetine plasma levels; 4 of the 22 infants (18%) had a plasma level greater than 10% of the mothers' which was defined by the authors as being elevated.[6]

An infant whose mother restarted fluoxetine at 63 days postpartum had blood drawn after 2 days of breastfeeding. The infant's fluoxetine level was 340 mcg/L and norfluoxetine was 208 mcg/L.[18]

A mother took fluoxetine 40 mg daily during pregnancy and postpartum. Infant blood samples were taken two times. The first was at approximately 11 days of age. The fluoxetine concentration was less than 40 mcg/L and norfluoxetine was 142 mcg/L. Eight days later after breastfeeding was discontinued, the infant's fluoxetine concentration was less than 40 mcg/L and norfluoxetine was 86 mcg/L.[19]

Eleven breastfed (6 exclusively; 5 supplemented) infants with an average age of 24.6 weeks (range 5 to 36 weeks) whose mothers were taking an average of 27.3 mg daily of fluoxetine all had measurable norfluoxetine serum levels averaging 3.2 mcg/L (range 1.4 to 8.7 mcg/L) which was 3.2% of average maternal norfluoxetine serum levels. One infant also had a detectable fluoxetine level of 2.6 mcg/L.[20]

The breastfed (extent not stated) infants of 11 women taking fluoxetine 20 to 40 mg daily during pregnancy and lactation had trough milk fluoxetine and norfluoxetine levels measured on day 4, week 2 and month 2 postpartum. At 2 weeks of age, fluoxetine was detectable in the serum of 2 of the infants in concentrations of 7.1% of the average maternal serum level. Norfluoxetine was detectable in the serum of all infants in average concentrations of 38% of the average maternal serum level. At 2 months of age, no infant had detectable fluoxetine levels; norfluoxetine was detectable in the serum of all infants in concentrations averaging 6.5% of the average maternal serum level.[7]

At 2 months postpartum, the breastfed infants of 7 mothers taking an average of 24 mg of fluoxetine daily had an average serum levels of 2 mcg/L of fluoxetine and 8.5 mcg/L of norfluoxetine which was about 9% of the maternal serum norfluoxetine level.[9]

Thirty serum levels were obtained from 23 infants with an average age of 3.7 months and breastfed an average of 91% by mothers who had been taking fluoxetine in an average dose of 21 mg daily for at least 4 weeks. Six of 7 infants had detectable serum levels in the first month, 6 of 8 in the second month and 2 of 14 thereafter. The ratio of infant to maternal serum levels of fluoxetine plus S-norfluoxetine dropped rapidly during the first month and was less than 10% by 2 months of age. Infant serum levels of S-fluoxetine and S-norfluoxetine were about 3

times as high as the R-isomers during the first 2 months. Only norfluoxetine could be detected after this time and the S- to R-isomer ratio fell to about 1.4.[10]

A woman was taking fluoxetine 40 mg daily during pregnancy and postpartum for depression. She breastfed (extent not stated) her infant. The infant had fluoxetine and norfluoxetine concentrations at age 7 days of 17.2 and 108 mcg/L, respectively.[21] It is likely that a portion of this concentration is attributable to placental transfer.

Effects in Breastfed Infants

Colic, decreased sleep, vomiting and watery stools occurred in a 6-day-old breastfed infant probably caused by maternal fluoxetine.[18] Two other reports of colic in breastfed infants, a 1.76-month-old and a 2-month-old, were possibly caused by fluoxetine in breastmilk. The older of the two also exhibited hyperactivity.[11]

Another case of possible increased irritability in a 3-month-old was noted by a pediatrician observer, who was the infant's father. However, the mother and the infant's pediatrician disagreed.[22]

Occurrence of hyperglycemia and glycosuria in a 5-month-old, possibly from fluoxetine in breastmilk was reported to the Australian Adverse Drug Reaction Advisory Committee.[23]

A 3-day-old breastfed infant was difficult to arouse, ceased rooting behavior, decreased nursing, and was moaning and grunting. Although the infant had been exposed in utero and was somewhat drowsy during the first 2 days of life, symptoms became worse after the mother's milk came in on day 3. These effects were probably caused by fluoxetine in breastmilk.[19]

Possible drug-induced seizure-like activity and cyanosis occurred in a breastfed 3-week-old breastfed infant whose mother was taking fluoxetine, carbamazepine and buspirone during pregnancy and breastfeeding.[24]

One observational report of 4 infants found no apparent neurological abnormalities following exposure to fluoxetine in milk for 12 to 52 weeks.[25]

A retrospective, case-control, cohort study compared the weights of the infants of mothers who took fluoxetine during pregnancy and breastfed for at least 2 weeks postpartum to the infants of mothers who took fluoxetine during pregnancy and did not breastfeed. Compared to controls, decreased weight gain occurred among the 26 infants exposed postpartum to fluoxetine in breastmilk, although the weights were still in the normal range.[26]

A prospective study of 51 nursing women taking fluoxetine and 63 nursing women who took no fluoxetine found no effect on weight gain, but reported a greater frequency of unspecified side effects in the infants of mothers who took fluoxetine.[27] This study's results have been reported only in abstract form, so some details are lacking.

In a prospective study of 40 women who took fluoxetine throughout pregnancy, 21 breastfed their infants (extent and duration not stated). Testing of the infants at 15 to 71 months of age found no differences in cognitive, language or temperament measurements between infants who were breastfed and those who were not.[28]

In a study comparing the 31 infants of depressed mothers who took an SSRI during pregnancy for major depression with 13 infants of depressed mothers who did not take an SSRI, mental development and most motor development in both groups was normal at follow-up averaging 12.9 months. Three of the treated mothers took fluoxetine in doses averaging 23.3 mg daily for an average of 3 months while breastfeeding their infants. Psychomotor development was slightly delayed compared to controls, but the contribution of breastfeeding to abnormal development could not be determined.[29]

Platelet serotonin levels were measured in 11 mothers and their breastfed infants after 4 to 12 weeks of fluoxetine therapy. Platelets and neurons both have the same serotonin transporter, so this effect on platelet serotonin

might indicate potential effects on the nervous system of some breastfed infants. Maternal fluoxetine dosages ranged from 20 to 40 mg daily. Ten of the infants were under 6 months of age and 4 were under 3 months of age at the start of therapy; 6 were exclusively breastfed. Although maternal platelet serotonin levels were decreased from 157 mcg/L to 23 mcg/L by fluoxetine therapy, average infant serotonin levels were 217 mcg/L before and 230 mcg/L after maternal therapy. These findings indicate that the amount of fluoxetine ingested by the infants was not sufficient to affect serotonin transport in platelets in most breastfed infants. However, 3 infants experienced drops in platelet serotonin of 13, 24 and 60%, respectively. The latter infant was the only one with measurable fluoxetine plasma levels as well as norfluoxetine, but the infant had no discernible adverse effects. One other infant had a delay in motor development at 24 weeks, but had normal mental development; 6 other infants were within 1 standard deviation of normal in both measures when tested between 24 and 56 weeks of age.[20]

Twenty-nine mothers who took fluoxetine in an average dosage of 34.6 mg daily for depression or anxiety starting no later than 4 weeks postpartum, breastfed their infants exclusively for 4 months and at least 50% during months 5 and 6. Their infants had 6-month weight gains that were normal according to national growth standards and mothers reported no abnormal effects in their infants.[30]

One study of side effects of SSRI antidepressants in nursing mothers found no adverse reactions that required medical attention in one infant whose mother was taking fluoxetine. No specific information on maternal fluoxetine dosage, extent of breastfeeding or infant age was reported.[31]

Eleven infants who were breastfed (extent and duration not stated) during maternal use of fluoxetine for depression (n = 5) or panic disorder (n = 6) had normal weight gain at 12 months of age that was not significantly different from a control group of infants whose mothers took no psychotropic medications. Neurologic development was also normal at 12 months of age.[7]

In 1 breastfed (extent not stated) infant aged 11 weeks whose mother was taking fluoxetine 20 mg daily, no adverse reactions were noted clinically at the time of the study.[8]

A small study compared the reaction to pain in infants of depressed mothers who had taken an SSRI during pregnancy alone or during pregnancy and nursing to a control group of unexposed infants of nondepressed mothers. Infants exposed to an SSRI either prenatally alone or prenatally and postnatally via breastmilk had blunted responses to pain compared to control infants. Seven of the 30 infants were exposed to fluoxetine. Because there was no control group of depressed, nonmedicated mothers, an effect due to maternal behavior caused by depression could not be ruled out. The authors stressed that these findings did not warrant avoiding drug treatment of depression during pregnancy or avoiding breastfeeding during SSRI treatment.[9]

An infant was born to a mother taking fluoxetine 40 mg daily, oxycodone 20 mg 3 times daily, and quetiapine 400 mg 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.[32]

An uncontrolled online survey compiled data on 930 mothers who nursed their infants while taking an antidepressant. Infant drug discontinuation symptoms (e.g., irritability, low body temperature, uncontrollable crying, eating and sleeping disorders) were reported in about 10% of infants. Mothers who took antidepressants only during breastfeeding were much less likely to notice symptoms of drug discontinuation in their infants than those who took the drug in pregnancy and lactation.[33]

A cohort of 247 infants exposed to an antidepressant in utero during the third trimester of pregnancy were assessed for poor neonatal adaptation (PNA). Of the 247 infants, 154 developed PNA. Infants who were

exclusively given formula had about 3 times the risk of developing PNA as those who were exclusively or partially breastfed. Fifteen of the infants were exposed to fluoxetine in utero.[34]

A late preterm infant was born to a mother who took fluoxetine 60 mg daily throughout pregnancy and during exclusive breastfeeding. At 7 days of age, the infant was found to be having jerking movements, with hypertonia and hyperreflexia as well as tachypnea and compensated metabolic acidosis. The infant's Finnegan scores were the range of 7 to 10. On day 8 of life, the infant had a serum fluoxetine level of 120 mcg/L, which is similar to therapeutic adult levels. Breastfeeding was discontinued and after 5 days of formula feeding the infant's Finnegan scores had decreased to a range of 3 to 6. After 10 days of formula, most symptoms had subsided. At 3 months of age, the infant was growing and developing normally. The infant's symptoms were attributed to serotonin syndrome caused by the high levels of fluoxetine rather than to withdrawal.[35] The reaction was probably caused by fluoxetine and breastfeeding might have contributed to maintaining the high fluoxetine levels after birth.

A woman with narcolepsy took sodium oxybate 4 grams each night at 10 pm and 2 am as well as fluoxetine 20 mg and cetirizine 5 mg daily throughout pregnancy and postpartum. She breastfed her infant except for 4 hours after the 10 pm oxybate dose and 4 hours after the 2 am dose. She either pumped breastmilk or breastfed her infant just before each dose of oxybate. The infant was exclusively breastfed, or breastmilk fed for 6 months when solids were introduced. The infant was evaluated at 2, 4 and 6 months with the Ages and Stages Questionnaires, which were withing the normal range as were the infant's growth and pediatrician's clinical impressions regarding the infant's growth and development.[36]

Two women were treated with fluoxetine 20 mg daily during the third trimester of pregnancy and during breastfeeding. Pediatric evaluations including neurologic assessments and brain ultrasound were conducted during the first 24 hours postpartum. Further follow-up was conducted at 6 or more months of age. Infant clinical status was comparable to unexposed infants from the same pediatric department.[17]

A woman was taking fluoxetine 40 mg daily during pregnancy and postpartum for depression. She breastfed (extent not stated) her infant. A venous cord gas taken at delivery showed a pH of 7.38. At 45 minutes postpartum, the baby developed respiratory distress syndrome with mixed respiratory and metabolic acidosis, becoming cyanosed and floppy requiring admission to the neonatal unit. Glucose was 3.4 mmol/L on admission. Abnormal movements, tremor, and extensor posturing were present initially, but resolved within hours, although irritability and poor sleep were noted subsequently. The mother discontinued breastfeeding and the infant's symptoms improved, although the infant had low levels of fluoxetine and norfluoxetine in his blood. The infant was discharged at age 16 days of age. The authors attributed the infant's symptoms to a serotonin syndrome caused by fluoxetine.[21]

In a retrospective cohort study of 5,079 newborns whose mothers took an SSRI during pregnancy, 1.5% of breastfed newborns had neonatal withdrawal compared with 2.3% among the formula-fed newborns, although this did not reach statistical significance. Breastfed newborns had a reduced risk of transfer to the NICU than formula-fed newborns; however, this finding did not persist in sensitivity analysis. Twelve percent of women in the study were taking fluoxetine.[37] A further analysis of these data indicated that infants of mothers who took a SSRI during pregnancy and exclusively breastfed had a greater risk of an emergency department visit or readmission to the hospital, primarily due to jaundice.[5]

A secondary analysis of a population study evaluated infant IQ scores with SSRI use postpartum during nursing (n = 22), non-SSRI exposed breastfed infants (n = 37), and non-breastfed infants (n = 38). Of the entire group of mothers, 81 mothers were treated with fluoxetine, 9 with sertraline, 8 with paroxetine, and 2 with citalopram. Children had IQ testing at a mean age of 4.9 years. There were no significant differences in any adjusted mean IQ scores between breastfed children with and without postnatal SSRI exposure.[38]

A pilot study compared the stool of breastfed infants whose mothers were taking an SSRI antidepressant to those of infants whose mothers were not taking an SSRI. Two of the 10 women taking an SSRI were taking fluoxetine. The stools of infants exposed to an SSRI in milk had increases in the genera *Gemella*, *Staphylococcus* and *Corynebacterium* and a decrease in *Lactobacillus*.[39]

Effects on Lactation and Breastmilk

Fluoxetine has caused increased prolactin levels and galactorrhea in nonpregnant, nonnursing patients.[40-48] Euprolactinemic galactorrhea has also been reported.[49] In a study of cases of hyperprolactinemia and its symptoms (e.g., gynecomastia) reported to a French pharmacovigilance center, fluoxetine was found to have a 3.6-fold increased risk of causing hyperprolactinemia compared to other drugs.[44] Preliminary animal and in vitro studies found that fluoxetine may have some estrogenic activity.[45] The prolactin level in a mother with established lactation may not affect her ability to breastfeed.

In a small prospective study, 8 primiparous women who were taking a serotonin reuptake inhibitor (SRI; 3 taking fluoxetine and 1 each taking citalopram, duloxetine, escitalopram, paroxetine or sertraline) were compared to 423 mothers who were not taking an SRI. Mothers taking an SRI had an onset of milk secretory activation (lactogenesis II) that was delayed by an average of 16.7 hours compared to controls (85.8 hours postpartum in the SRI-treated mothers and 69.1 h in the untreated mothers), which doubled the risk of delayed feeding behavior compared to the untreated group. However, the delay in lactogenesis II may not be clinically important, since there was no statistically significant difference between the groups in the percentage of mothers experiencing feeding difficulties after day 4 postpartum.[46]

A case control study compared the rate of predominant breastfeeding at 2 weeks postpartum in mothers who took an SSRI antidepressant throughout pregnancy and at delivery (n = 167) or an SSRI during pregnancy only (n = 117) to a control group of mothers who took no antidepressants (n = 182). Among the two groups who had taken an SSRI, 33 took citalopram, 18 took escitalopram, 63 took fluoxetine, 2 took fluvoxamine, 78 took paroxetine, and 87 took sertraline. Among the women who took an SSRI, the breastfeeding rate at 2 weeks postpartum was 27% to 33% lower than mother who did not take antidepressants, with no statistical difference in breastfeeding rates between the SSRI-exposed groups.[47]

An observational study looked at outcomes of 2859 women who took an antidepressant during the 2 years prior to pregnancy. Compared to women who did not take an antidepressant during pregnancy, mothers who took an antidepressant during all 3 trimesters of pregnancy were 37% less likely to be breastfeeding upon hospital discharge. Mothers who took an antidepressant only during the third trimester were 75% less likely to be breastfeeding at discharge. Those who took an antidepressant only during the first and second trimesters did not have a reduced likelihood of breastfeeding at discharge.[50] The antidepressants used by the mothers were not specified.

A retrospective cohort study of hospital electronic medical records from 2001 to 2008 compared women who had been dispensed an antidepressant during late gestation (n = 575; fluoxetine n = 21) to those who had a psychiatric illness but did not receive an antidepressant (n = 1552) and mothers who did not have a psychiatric diagnosis (n = 30,535). Women who received an antidepressant were 37% less likely to be breastfeeding at discharge than women without a psychiatric diagnosis, but no less likely to be breastfeeding than untreated mothers with a psychiatric diagnosis.[51]

In a study of 80,882 Norwegian mother-infant pairs from 1999 to 2008, new postpartum antidepressant use was reported by 392 women and 201 reported that they continued antidepressants from pregnancy. Compared with the unexposed comparison group, late pregnancy antidepressant use was associated with a 7% reduced likelihood of breastfeeding initiation, but with no effect on breastfeeding duration or exclusivity. Compared with the unexposed comparison group, new or restarted antidepressant use was associated with a 63% reduced

likelihood of predominant, and a 51% reduced likelihood of any breastfeeding at 6 months, as well as a 2.6-fold increased risk of abrupt breastfeeding discontinuation. Specific antidepressants were not mentioned.[52]

Alternate Drugs to Consider

Nortriptyline, Paroxetine, Sertraline

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Substance Identification

Substance Name

Fluoxetine

CAS Registry Number

54910-89-3

Drug Class

Breast Feeding

Lactation

Milk, Human

Antidepressive Agents

Serotonin Uptake Inhibitors