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Vitamin B_6

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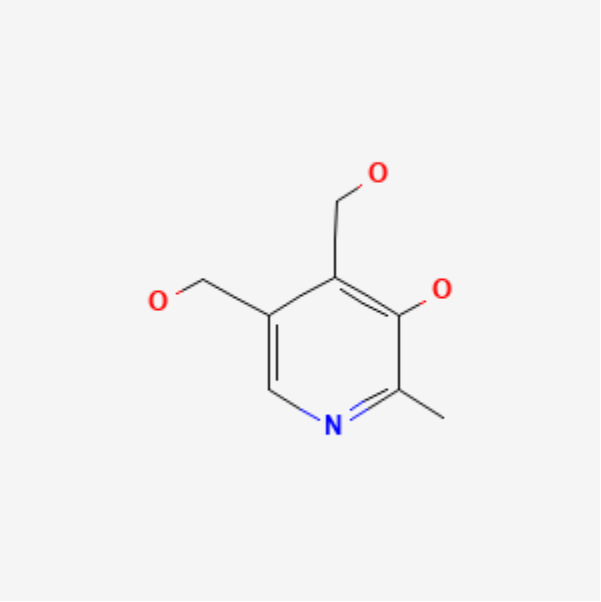

Drug Levels and Effects

Summary of Use during Lactation

Vitamin B_6 (pyridoxine) is an essential nutrient in the human diet and is naturally found in human milk. Maternal supplementation increases milk levels in a dose-dependent manner. The recommended maternal minimum daily pyridoxine intake during pregnancy and lactation is 2 mg. The recommended adequate daily intake for neonates and infants up to 6 months of age is 0.1 mg.[1-3] Intakes of 1 to 2 mg/kg pyridoxine daily are considered safe for neonates and infants receiving isoniazid for treatment or prevention of tuberculosis infection.[4] Mothers taking a supplemental dose of 7.5 to 20 mg daily to prevent or treat B_6 deficiency should have milk levels that provide an adequate B_6 intake for the exclusively breastfed infant. Lower doses increase milk levels somewhat, but not necessarily sufficient. Higher doses of 100 to 200 mg daily used to prevent or treat some B_6-responsive diseases have not been studied during lactation, but would not be expected to expose

breastfed infants to a harmful amount. High-dose pyridoxine does not appear to be effective for lactation suppression.

Drug Levels

Vitamin B_6 refers to six similar natural isomers or vitamers; pyridoxine, pyridoxamine, pyridoxal, and each of their 5'-phosphorylated forms. After ingestion, the non-phosphorylated forms are absorbed well from the gastrointestinal tract. Each B_6 vitamer can be enzymatically converted to the active form, pyridoxal 5′-phosphate.[5,6] Pyridoxal and pyridoxal 5′-phosphate account for approximately 70% and 15%, respectively, of vitamin B_6 in human milk. Pyridoxine, pyridoxamine and their 5'-phosphate analogs are nearly evenly distributed among the remaining 15%.[7-10] Pyridoxine is the vitamer most often used medicinally and in multivitamin supplements because it is the most chemically stable.

Maternal Levels. Average total vitamin B_6 concentrations are 800 to 1200 nmoL/L (140 to 200 mcg/L) in mature milk at 2 to 6 months postpartum among healthy mothers with adequate dietary intake and biochemical status not taking a B_6 supplement.[8,10,11] Maternal B_6 dietary intake and biochemical status positively influence milk levels.[12,13] Mothers with inadequate B_6 intake or low status have reported average total B_6 levels of 300 to 400 nmoL/L (50 to 70 mcg/L) in mature milk.[3,8] Low vitamin B_6 status is defined biochemically as a blood plasma pyridoxal 5′-phosphate (PLP) level < 20 nmoL/L (<5 mcg/L).

Milk levels increase after birth with each stage of lactation. Reported colostrum levels are approximately 2-to-5-fold lower compared to after two weeks postpartum. Levels plateau by 2 to 6 months postpartum and thereafter gradually decline.[13-16] Foremilk and hindmilk levels are believed to be similar, although this has only been evaluated in two study subjects.[17] Two studies have reported 50% lower average levels in milk from mothers after preterm birth compared to those giving birth at term gestation, although underlying maternal B_6 status was not evaluated.[14,15]

Low daily maternal doses of 2 to 4 mg pyridoxine supplementation results in milk levels similar to or slightly higher (200 to 300 mcg/L) than nonsupplemented mothers (140 to 200 mcg/L). Higher daily maternal doses of 10 to 30 mg are required to increase milk levels to near or above 500 mcg/L. At these higher dosages, exclusively breastfed infants could be exposed to 0.2 to 0.4 mg pyridoxine daily which is slightly higher than the minimal adequate daily intake of 0.1 mg, but still well below the infant treatment dose of 1 to 2 mg/kg daily.

Twenty-two exclusively breastfeeding women in North Carolina with normal B_6 status participating in a study of postpartum weight loss and exercise were given a multivitamin supplement with 2 mg of pyridoxine once daily beginning at 4 to 6 weeks postpartum. Average total B_6 levels in milk increased from 800 nmol/L (140 mcg/L) at baseline to 1000 nmol/L (170 mcg/L) when measured at 9 to 11 weeks.[18]

Ten postpartum women in Texas received an oral multivitamin tablet supplement containing 4 mg of pyridoxine beginning on the day of delivery. Foremilk and maternal blood was sampled on postpartum days 5 to 7 and again on days 43 to 45. Seven women who were not given a supplement served as a control group. All of the participants had adequate vitamin B_6 status. At the first measurement, reported average milk total B_6 levels were 225 mcg/L in the supplemented group and 128 mcg/L in the nonsupplemented group. At the second measurement, average levels were 237 and 204 mcg/L, respectively.[19] The same research group conducted a similar study in 12 different postpartum women with adequate baseline B_6 status. Supplementation with a multivitamin containing 4 mg of pyridoxine was initiated 1 to 3 months postpartum; 6 received the daily supplement and 6 did not. At 6 months postpartum, average milk vitamin B_6 levels were 235 and 212 mcg/L, respectively.[11] These studies indicate that low dose early postnatal pyridoxine supplementation can increase colostrum pyridoxine levels, but produce only modest changes in mature milk levels.

Eighteen postpartum women in Indiana with established lactation were given an oral multivitamin containing either 2.5, 10, or 20 mg pyridoxine to take once daily for three days. Six other postpartum women were given no

supplement as a control group. All participants had similar dietary vitamin B_6 intake, but baseline vitamin B_6 status was not measured. Foremilk was collected at regular intervals throughout the 3-day study period. Average vitamin B_6 levels among all the milk samples were 550, 1130, 1460, and 2440 nmol/L (90, 190, 250, and 410 mcg/L) in the no supplement, 2 mg, 10 mg, and 20 mg groups, respectively.[20] Based on these results, an exclusively breastfed infant would receive 0.06 mg/kg of pyridoxine daily from the 3-day course of 20 mg daily maternal pyridoxine supplement. This likely underestimates the infant exposure with ongoing maternal dosing beyond 3 consecutive days.

Forty-seven postpartum women in Indiana who reported taking a pyridoxine supplement during pregnancy were given an oral multivitamin containing either 2.5, 4, 7.5, or 10 mg pyridoxine to take once daily beginning after lactation was established. A 10 mL sample of milk was collected by the mothers using manual expression or a breast pump with each breastfeeding over a 24-hour period at monthly intervals between 1 and 6 months postpartum. Maternal blood was sampled at 1, 4, and 6 months postpartum for PLP measurement. Maternal dietary intakes were similar between groups during the study period. Average milk levels increased over the 6 month collection period from 800 to 1200 nmoL/L (140 to 200 mcg/L), 1200 to 1800 nmoL/L (200 to 300 mcg/L), 1800 to 2400 nmoL/L (300 to 400 mcg/L), and 1800 to 3000 nmoL/L (300 to 500 mcg/L) in the 2.5, 4, 7.5, and 10 mg groups, respectively, plateauing by 2 months in the low dose 2.5 mg group, and by 4 months in the three higher dose groups. Peak milk levels occurred 1 to 2 hours after supplement administration in the 2.5 mg group, and 3 to 4 hours after administration in the other three groups. B_6 levels were not significantly different between the 7.5 and 10 mg groups. The highest measured peak milk level was 4400 nmoL/L (750 mcg/L) in the 10 mg group at 4 months postpartum. Milk levels were positively correlated with maternal plasma PLP levels, which were higher in the higher dose groups.[13] Based on the average milk levels reported in this study, an exclusively breastfed infant would receive 0.03 mg/kg daily from a 2.5 mg daily maternal pyridoxine supplement, and 0.08 mg/kg daily from a 10 mg daily maternal supplement.

Twenty postpartum women in Oklahoma were randomized to receive pyridoxine 2 mg or 27 mg once daily for 28 days beginning in the first week postpartum. Foremilk was collected for one 24-hour period on study days 7, 14, and 28. Dietary intakes of vitamin B_6 during the study period were similar between the two groups. Average total vitamin B_6 levels in milk at day 28 were 700 nmol/L (120 mcg/L) and 3200 nmol/L (540 mcg/L) in the 2 mg and 27 mg groups, respectively.[9] Based on these results, an exclusively breastfed infant would be exposed to pyridoxine 0.08 mg/kg daily from a 27 mg daily maternal supplement.

Forty mothers in Maryland were randomly given a once daily vitamin-mineral supplement containing 0.5 or 4 mg pyridoxine beginning the day after delivery and continuing for 9 months. Prenatal daily vitamins with 4 mg pyridoxine were used in all participants during pregnancy, and the estimated average dietary vitamin B_6 intake was similar between the two groups at approximately 1.5 mg daily throughout the postpartum study period. Milk was collected at 1 and 2 weeks, and at 1, 3, 6, and 9 months postpartum. Thirty mothers remained in the trial at 6 months but only seventeen by 9 months. Average milk levels were approximately 500 nmol/L (85 mcg/L) and 1000 nmol/L (170 mcg/L) at 1 week in the 0.5 mg and 4 mg groups, respectively. Milk levels increased sharply to 1200 nmol/L (200 mcg/L) and 2200 nmol/L (370 mcg/L), respectively, by 1 month and then plateaued by 3 months at 1500 nmol (250 mcg/L) and 2300 nmoL (390 mcg/L), respectively.[21] Based on the average milk values at 3 months, an exclusively breastfed infant would be exposed to pyridoxine 0.04 mg/kg daily and 0.06 mg/kg daily from a 0.5 mg and 4 mg, respectively, daily maternal supplemental pyridoxine dose.

Seventeen postpartum lactating women in Indiana were given either a 2.5 mg or 15 mg daily pyridoxine supplement beginning on the day of hospital discharge. Prior to entering the study, all participants had been taking prenatal vitamins containing vitamin B_6 and had normal vitamin B_6 status at baseline. Foremilk was collected at 1, 2, 4, and 6 months postpartum. Mean maternal dietary vitamin B_6 intake was similar between the two groups over the 6-month study period. The average total vitamin B_6 milk content increased over the course of the study from 148 mcg/L to 212 mcg/L in the 2.5 mg group, and from 374 mcg/L to 534 mcg/L in the 15 mg

group.[22] Although there was no nonsupplemented breastfed control group, the milk concentrations reported in the lower 2.5 mg dose group are similar to those reported in other studies of nonsupplemented healthy mothers. Based on these results, an exclusively breastfed infant would be exposed to 0.08 mg/kg daily from a 15 mg daily maternal supplemental pyridoxine dose. The same investigators repeated the study in a different group of lactating women using an updated assay capable of measuring individual B_6 vitamers in milk. Eight participants were given 2.5 mg pyridoxine once daily, nine were given 15 mg, and two did not take a supplement. Each participant collected a small quantity of foremilk prior to each feeding over a 24-hour period at approximately 1 month postpartum. Pyridoxal was the dominant vitamer, providing 60 to 80% of total B_6 milk content, in all three groups milk samples at all time points. Total B_6 milk levels ranged from a low of approximately 730 nmol/L (120 mcg/L) prior to supplement administration, to a high of 1300 nmol/L (220 mcg/L) between 3 and 8 hours after supplement administration in the 2.5 mg group, and from 1600 to 4100 nmol/L (270 to 700 mcg/L) in the 15 mg group, respectively. Average levels from all collected samples were not reported. Milk levels did not fluctuate significantly over the 24-hour collection period in the two nonsupplemented participants, whose average milk levels were about 800 nmol/L (140 mcg/L).[23]

Eighteen lactating women in Bangladesh who were between 2 and 4 months postpartum were given a multinutrient supplement capsule containing pyridoxine 3 mg once in the morning with breakfast, and then two capsules the following morning. Milk was collected with every feeding from the same breast beginning 24 hours prior to starting supplementation and continuing until 24 hours after the two capsules were given for a total collection period of 72 hours. Median milk pyridoxal levels in each 24-hour period increased from 87 mcg/L at baseline to 214 mcg/L after the 6 mg supplementation. B_6 levels peaked between 2 and 8 hours after a dose. The maximum reported level was 683 mcg/L, at approximately 4 hours after the 6 mg dose.[24] The main objective of this study was to document daily fluctuations in milk vitamin levels pre- and post-supplementation, which would identify ideal times for sample collection when designing vitamin supplementation studies. Based on the median levels reported in this study, an exclusively breastfed infant would be exposed to 0.03 mg/kg daily of pyridoxal from a two-day maternal regimen of 3 mg followed by 6 mg. This likely underestimates the infant exposure with ongoing maternal dosing beyond two consecutive days.

Twenty-eight lactating women in Guatemala who were between 4 and 6 months postpartum were randomized to receive a multinutrient supplement containing 3.8 mg of pyridoxal in either daily or divided doses, or no supplement. Both methods of supplement delivery resulted in similar average milk pyridoxal levels over an 8-hour milk collection period of approximately 200 mcg/L, compared to 150 mcg/L in the control group.[25] Based on the average levels reported in this study, an exclusively breastfed infant would be exposed to 0.03 mg/kg daily of pyridoxal from a 3.8 mg daily maternal dose.

Infant Levels. Twenty postpartum women in Oklahoma were randomized to receive pyridoxine 2 mg or 27 mg once daily for 28 days beginning in the first postpartum week. Their infants were exclusively fed maternal milk during the 28-day study period. One-half of the infants in the 2 mg maternal supplement group were given a daily multivitamin containing 0.4 mg pyridoxine, presumably started when breastfeeding was established, although this was not stated. In addition to cord blood, maternal and infant blood was collected for assessment of B_6 status on day 7, 14, and 28. Maternal dietary intakes of vitamin B_6 during the study period were similar between the two groups. Average infant plasma PLP levels in the 2 mg maternal dose group decreased from 114 nmol/L in cord blood to approximately 40 nmol/L on study days 7, 14, and 28 (normal ≥20 nmol/L). In the 27 mg maternal dose group, plasma PLP levels decreased from 171 nmol/L in cord blood to approximately 110 nmol/L at 7 days, then increased to 160 nmol/L on day 14, and to 200 nmol/L on day 28. Levels in the supplemented infant group were similar to the high maternal dose group, except for slightly higher levels of approximately 250 nmol/L on days 14 and 28. Infant vitamin B_6 status was correlated with maternal B_6 supplemental dose and status.[9]

Seventeen postpartum lactating women in Indiana were given either a 2.5 mg or 15 mg daily pyridoxine supplement beginning on the day of hospital discharge. Prior to entering the study, all maternal participants had been taking routine prenatal vitamins containing vitamin B_6 and had normal vitamin B_6 status. Serum was collected from infants for PLP measurements at baseline 15 days postpartum, and again at 1, 4, and 6 months postpartum. Average maternal dietary vitamin B_6 intake, and infant solid food B_6 intake, was similar between the two groups over the 6-month study period. Average infant plasma PLP levels were 73 nmol/L at baseline (normal ≥20 nmol/L) and remained stable in the 2.5 mg maternal supplemental group, but increased to approximately 200 nmol/L in the 15 mg maternal supplemental group.[22]

Effects in Breastfed Infants

Twenty postpartum women in Oklahoma were randomized to receive pyridoxine 2 mg or 27 mg once daily for 28 days beginning in the first postpartum week. One-half of the infants in the 2 mg maternal supplement group were given a daily multivitamin containing 0.4 mg pyridoxine, presumably started when breastfeeding was established, although this was not stated. Maternal dietary intakes of vitamin B_6 during the study period were similar between the two groups. Weekly changes in weight and length Z scores were correlated with infant pyridoxine intake. Increases in weight and length Z scores over the course of the 28-day study period were similar between the directly supplemented infants and infants of mothers supplemented with 27 mg, and both were greater than nonsupplemented infants of mothers supplemented with 2 mg. However, these differences were clinically unimportant.[9]

Seventeen postpartum lactating women in Indiana were given either a 2.5 mg or 15 mg daily pyridoxine supplement beginning on the day of hospital discharge and continued for 6 months, during which time their infants were exclusively breastfed. Prior to entering the study, all maternal participants had been taking routine prenatal vitamins containing vitamin B_6 and had normal vitamin B_6 status at baseline. In 15 of the infants, weight and length were measured at birth, and again at 1, 4, and 6 months postpartum. Both were similar between the two groups at all time points.[22]

Forty-four term, healthy infants in Finland were prospectively followed for growth and vitamin B_6 status beginning at birth and continuing through the first 12 months postpartum. All mothers followed World Health Organization guidelines at the time which involved exclusive breastfeeding for 6 months after birth, introducing supplemental solid foods at 6 months, and waiting to wean from breastfeeding until 9 months. At 12 months all the infants were still partly breastfed. All mothers were given a 1 mg pyridoxine supplement to take once daily beginning on postpartum day 5 and most took a pyridoxine supplement during pregnancy. Maternal vitamin B_6 status was not reported. Seven of the 44 infants developed low B_6 status during the first 6 months postpartum. Between 6 and 9 months those 7 infants had lower weight-for-age, and length grew more slowly than study infants with adequate status. By 10 to 12 months of age, there were no longer differences.[26] This and other studies by the same group.[27] suggest that exclusive breastfeeding carries a risk of infant low vitamin B_6 status and poor growth, despite low-dose maternal supplementation.

A term, otherwise healthy newborn developed tremors in the arm, leg, and chin shortly after delivery. The infant had been put to breast one time prior to the onset of tremors. Biochemical tests of the infant's blood were all within normal limits except their serum vitamin B_6 was five times the upper normal limit. The mother's serum vitamin B_6 was twice the upper normal limit. The mother had been taking daily prenatal vitamins containing 4 mg of pyridoxine during pregnancy. Upon discontinuation of the maternal supplement, the infant's serum B_6 level decreased to near the upper normal limit within a month, symptoms gradually improved, and abnormal EEG findings at 2 months of age resolved by 6 months of age.[28] Since the infant in this case only breastfed once and likely consumed only small amounts of colostrum, which has much lower levels of vitamin B_6 than mature milk, this case likely involves vitamin B_6 toxicity from transplacental exposure and not breastfeeding exposure. Considering the mother was not taking a high prenatal dose, this case also suggests some form of genetic variation in vitamin B_6-dependent or metabolizing proteins in the mother and/or infant, which was not

tested. Discontinuing maternal supplementation and reducing maternal dietary B_6 intake, but continuing to breastfeed, is a reasonable approach in such a situation, since infant formula is likely to have a higher amount of vitamin B_6.

Effects on Lactation and Breastmilk

A systematic review found that two studies in the 1970s using very high maternal doses of 600 mg of pyridoxine daily in divided doses three times a day for 7 days begun shortly after delivery was effective at inhibiting lactation. However, these results have not been replicated in multiple other studies, nor has very high dose pyridoxine been demonstrated to reduce prolactin levels.[29] A second systematic review found dopaminergic agents to be superior to pyridoxine in suppressing postpartum lactation.[30]

A randomized, prospective, but nonmasked study compared cabergoline 1 mg (in one dose or 0.25 mg twice daily for 2 days; n = 45) to pyridoxine 200 mg 3 times daily for 7 days (n = 43) in suppressing lactation in postpartum women who did not wish to breastfeed. Treatment was initiated approximately 24 hours after delivery. Based on patient self-assessment, cabergoline was more effective than pyridoxine for suppressing lactation (78% vs 35%) and in reducing engorgement and pain (89% vs 67%) at day 7. The frequency of milk leakage was lower with cabergoline group after 7 and 14 days compared to pyridoxine (9% vs 42% and 11% vs 31%, , respectively). Headache and constipation were the most commonly reported adverse effects, occurring more frequently in cabergoline patients (15% vs 2%).[31]

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Substance Identification

Substance Name

Vitamin B_6

CAS Registry Number

65-23-6; 66-72-8

Drug Class

Breast Feeding

Lactation

Milk, Human

Vitamins