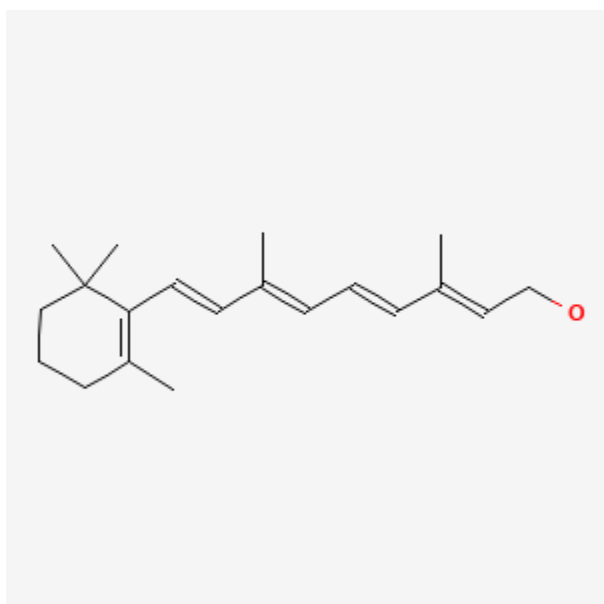




## Vitamin A

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CASRN: 68-26-8; 79-81-2



## Drug Levels and Effects

### Summary of Use during Lactation

Vitamin A (retinol) and provitamin A carotenoids are normal components of human milk.[1] Vitamin A in milk has antioxidant properties.[2] The recommend dietary intake in lactating women is 1300 mcg retinol daily, compared to 770 mcg daily during pregnancy. The recommended daily intake for infants aged 6 months or less is 400 mcg. Vitamin A deficiency is not uncommon, and maternal supplementation may be needed during lactation to achieve the recommended daily vitamin A intake. Maternal single doses up to 120,000 mcg (400,000 IU) or daily doses up to 1500 mcg (5,000 IU) are not expected to harm the breastfed infant. Higher maternal doses have not been studied. Daily maternal doses above 3,000 mcg (10,000 IU) should be avoided.[3]

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## Drug Levels

Vitamin A (retinol) measurements are expressed in the literature as mcg, IU, or micromoles. One mcg is equal to 3.33 IU (0.3 mcg = 1 IU), and also to 0.0035 micromoles (286 mcg = 1 micromole). Beta-carotene from vitamin supplements is one-half as potent as retinol. One mcg of beta-carotene from vitamin supplements is therefore equal to 0.5 mcg retinol (see the LactMed [beta-carotene](#) record). A serum retinol concentration less than 0.7 micromoles/L (<200 mcg/L) indicates biochemical vitamin A deficiency, and 0.7 to 1.05 micromoles/L (200 to 300 mcg/L) indicates marginal deficiency.[2] Milk levels less than 1.05 micromoles/L (<300 mcg/L) indicates low milk vitamin A content.[4]

Most retinol present in milk are retinyl esters (e.g., retinyl acetate), which can be de-esterified in the infant's digestive tract.[5] Mature milk retinol levels correlate with maternal serum retinol levels, and levels of milk retinol and beta-carotene are correlated with one another.[6-10] Milk retinol and carotenoid levels in colostrum are higher than in mature milk. Intra-individual colostrum levels vary widely, but are consistently higher than and not correlated with maternal serum levels, suggesting active colostrum enrichment.[11] Levels decrease over the first 1 to 2 weeks postpartum and then stabilize.[2,12,13] Vitamin A partitions into milk fat and milk retinol levels are positively correlated with milk fat.[9,14] Hindmilk levels are higher than foremilk.[15,16] Milk vitamin A content increases as maternal dietary vitamin A increases.[17] Nutritionally deficient mothers have lower milk retinol and provitamin A carotenoid levels than those of well-nourished mothers.[6,18,19] Premature birth may also be associated with lower milk retinol levels.[20,21]

*Maternal Levels.* Healthy mothers not taking a supplement have retinol levels averaging 800 to 1400 mcg/L in colostrum and 300 to 800 mcg/L in mature milk.[10,11,13,16,19,22,23] Beta-carotene, lutein and lycopene are among the most abundant carotenoids in milk, totaling 300 to 400 mcg/L in the first week postpartum and 50 to 200 mcg/L in mature milk.[1,10,12,13,19]

Numerous studies targeting lactating women living in regions with endemic vitamin A deficiency have evaluated the effects of a single vitamin A dose of 200,000 to 400,000 IU given in the early postpartum period. Most of these studies demonstrate small increases in milk retinol levels compared to the control or placebo group during the first 3 months postpartum. In a meta-analysis of six such studies, the average increase in milk retinol was 57 mcg/L in the mothers treated with vitamin A compared to placebo.[24] Studies that controlled for milk fat content had similar outcomes. In two of the analyzed studies, the frequencies of low milk levels (<300 mcg/L) were 25% and 50% lower in supplemented mothers compared to control. Based on the average increase in milk retinol reported in this meta-analysis, the single, high-dose vitamin A postpartum maternal supplementation strategy would provide breastfed infants with an extra 3.5 to 13 mcg/kg of retinol daily after the first postpartum week.

A study involving 102 mothers from Hyderabad, India given 200,000 IU of vitamin A within 24 hours of birth reported higher average milk retinol levels in the vitamin A group at postpartum day 10 (1100 mcg/L vs. 800 mcg/L), and day 30 (750 mcg/L vs 600 mcg/L), but not on or after day 45. The increase in milk retinol intake from maternal supplementation during the first month after birth for a breastfed infant based on these results would be about 30 mcg/kg daily.[23] In a similar study conducted in northeastern Brazil, average milk retinol was higher in the colostrum of the supplemented group 24 hours after the dose (2360 mcg/L vs 1010 mcg/L), but was not significantly different at 30 days (525 mcg/L vs. 478 mcg/L).[25]

A large study conducted in Ghana, Peru, and India gave vitamin A 200,000 IU or placebo to 2,990 breastfeeding mothers at 18 to 42 days postpartum. The average milk retinol level at baseline was similar in both groups (52.2 vs 51.6 nmol/gram of fat), but was higher at 2 months postpartum in the vitamin A group (49.8 vs. 42.7 nmol/gram of fat). The percentage of mothers at 2 months with milk retinol of 28 nanomoles/gram of fat or less, indicating low milk vitamin A content, was 49% in the treatment group compared to 79% in the placebo group. At 6 months postpartum, there were no differences between the groups.[26]

Studies comparing a 400,000 IU dose to a 200,000 IU dose of vitamin A have found no differences in milk vitamin A levels between the two dosage groups.[27-31]

One hundred forty healthy, low-income mothers in Rabat, Morocco were given 200,000 IU of vitamin A as a one-time dose beginning at 2 to 3 weeks after birth. In addition, the mothers were randomized to receive vegetable oil fortified with retinyl palmitate 30 IU per gram of oil, or non-fortified oil. The oil was to be used in the home during routine food preparation, not as a daily required study dose. Both groups had milk retinol levels near 515 mcg/L at baseline. After three months, average milk levels were 386 mcg/L in the nonfortified group and 592 mcg/L in the fortified group; 20% of mothers in the nonfortified group had low milk levels (<300 mcg/L) compared to none in the fortified group. After 6 months, the differences were 172 mcg/L vs. 398 mcg/L, and 100% vs. 2.7%, respectively.[32] Based on the average milk levels reported, exclusively breastfed infants would receive approximately an extra 30 mcg/kg retinol daily from the regimen used in this study.

Daily supplementation of 2165 IU vitamin A was compared to no supplementation in 119 Gambian pregnant and postpartum women. Milk retinol levels collected once weekly between postpartum weeks 3 and 15 were higher in the supplemented mothers, ranging from 800 to 1000 mcg/L, compared to 500 to 700 mcg/L in the non-supplemented mothers. Adjusting for milk fat content did not change the results.[33] Based on the milk levels reported, breastfed infants would receive an extra 45 mcg/kg retinol daily as a result of this long-term, pregnancy through postpartum extended supplementation approach.

Two hundred forty-five healthy, exclusively breastfeeding mothers in Nanjing, China were randomized to receive a daily vitamin A supplement of 1800 IU or placebo for 2 months beginning at 1 to 2 months postpartum. Both groups had similar average milk retinol levels of approximately 450 mcg/L at baseline. After two months, average milk level in the supplemented group was 290 mcg/L compared to 240 mcg/L in the control group. The difference amounts to an extra 7.5 mcg/kg retinol daily received by the breastfed infant from the short period of maternal supplementation.[23]

HIV-infected pregnant women with vitamin A deficiency or marginal deficiency in Tanzania were enrolled in a study to receive 1 of 4 supplements during pregnancy and lactation. Groups received either multivitamins (thiamine, riboflavin, vitamin B6, niacin, vitamin B<sub>12</sub>, vitamin C, vitamin E, and folic acid), multivitamins plus vitamin A 5000 IU and beta-carotene 30 mg, the same doses of vitamin A and beta-carotene alone, or placebo once daily beginning in their second trimester and continuing for two years. Breastmilk samples were collected at delivery and at 3-month intervals thereafter up to 1 year. Breastmilk retinol levels in the vitamin A and beta-carotene supplemented groups were consistently about 2 to 3 micromoles/L (570 to 860 mcg/L) higher during the entire study period than in the groups that received no supplement. The average milk levels were 1400 mcg/L vs 640 mcg/L at 3 months, 1350 mcg/L vs 640 mcg/L at 6 months, and 1300 mcg/L vs 630 mcg/L at 12 months. [34] Based on the maximum average retinol levels reported, an exclusively breastfed infant would receive an extra 114 mcg/kg daily of retinol from the maternal supplementation used in this study.

Premature birth may be associated with lower milk retinol levels. A southeastern Brazilian study of non-supplemented mothers reported average levels of 286 mcg/L at around 30 days postpartum in those who delivered preterm babies compared to 534 mcg/L in those delivering at term.[21] Similarly, in a study from Mexico of non-supplemented mothers who experienced high-risk pregnancies (e.g., preeclampsia, anemia, advanced maternal age or gestational diabetes), premature birth increased the odds of low milk retinol levels compared to term birth, and compared to mothers with normal pregnancies.[21]

*Infant Levels.* One hundred nine Indian mothers were given a single dose of vitamin A 200,000 IU or no vitamin A within 48 hours of delivery. At 3 months postpartum the average infant serum retinol level was higher (1.06 micromoles/L vs 0.77 micromoles/L) and the percentage of infants with serum levels <0.7 micromoles/L was lower (2.6% vs 44.8%) in the vitamin A group. One-half of all infants had umbilical cord retinol levels <0.7 micromoles/L, but differences between the two groups for this baseline measurement were not reported.[35]

One hundred forty Indonesian mothers were given a single oral dose of 300,000 IU vitamin A as retinyl palmitate or placebo between 7 and 21 days postpartum. Baseline infant serum retinol was not measured. At 6 months postpartum, average infant serum retinol levels did not differ between the two groups. However, the proportion of infants with levels <0.52 micromoles/L was lower in the treatment group, 15% vs 36%. Breastfeeding rates and infant diet were the same in both groups.[36]

One hundred forty mothers in Bangladesh were given 200,000 IU vitamin A or placebo between 1 and 3 weeks postpartum. Baseline infant serum retinol was not measured. Infant vitamin A dietary and supplemental intakes during the first 6 months of age were not different between the two groups. Infants were partially breastfed for 6 months, at which time the average infant serum retinol level was higher in the vitamin A group, 0.84 micromoles/L compared to 0.77 micromoles/L in the placebo group. Biochemical indicators of adequate infant vitamin A storage were also better in the vitamin A group.[37]

One hundred ten Gambian women were given 200,000 IU vitamin A shortly after delivery. Breastfeeding rates were not given, but >90% of participants were able to provide milk for study analysis during the 6 months postpartum milk collection period. Average infant serum retinol increased from 0.67 micromoles/L in cord blood to 0.85 micromoles/L at 9 months. The percentage of infants with levels <0.7 micromoles/L decreased from 61% at birth to 31% at 9 months.[27]

To compare a 200,000 IU to a 400,000 IU maternal dose, 173 Brazilian mothers were given 200,000 IU vitamin A once after delivery, or once after delivery and again at 10 days postpartum. Their infants were more than 75% breastfed for 6 months, but not supplemented with vitamin A directly. The average infant serum levels in umbilical cord blood and in blood at 2, 4 and 6 months postpartum were similar in both groups: 1.1, 1.2, 1.5, and 1.55 micromoles/L, respectively. The increase compared to baseline was statistically significant in both groups. This study suggests that a single high maternal dose of vitamin A can improve infant vitamin A status through breastmilk, but a 400,000 IU dose offered no added improvement in status over a 200,000 IU maternal postpartum dose.[38]

One hundred exclusively breastfeeding Indian mothers were given 200,000 IU vitamin A or placebo as a single oral dose within 24 hours after delivery. Average infant serum retinol levels increased from approximately 0.5 micromoles/L in cord blood to 0.8 to 0.9 micromoles/L at 6 weeks to 6 months in both groups.[22]

In Kenya, 564 mothers were given 400,000 IU vitamin A or placebo within 24 hours of birth. About 30% of the mothers were vitamin A deficient at study entry. Their infants were also randomized to receive 100,000 IU vitamin A or placebo at 14 weeks of age. The average serum retinol level was similar in all infants at 14 weeks of age, about 0.9 micromoles/L, and again at 26 weeks among all infants who received placebo, about 1.0 micromoles/L. The lack of a difference did not change when controlling for maternal baseline serum retinol. Breastfeeding rates were not reported.[39]

In Brazil, 61 breastfeeding mothers received 200,000 IU vitamin A or placebo between 20 and 30 days postpartum. At 3 months postpartum the average infant serum retinol levels were similar: 0.69 micromoles/L in the vitamin A group and 0.64 micromoles/L in the placebo group. Seventy-five percent of infants were exclusively breastfed throughout the study period.[8]

## Effects in Breastfed Infants

Maternal vitamin A supplementation during pregnancy and lactation has not reduced mortality or the risk of anemia in breastfed infants living in developing regions, but there may be health benefits related to improved antioxidant capacity and immune function.[24,40,41]

One hundred exclusively breastfeeding mothers in India were given 200,000 IU vitamin A or placebo as a single oral dose within 24 hours after delivery. There were no differences in weight gain of their infants during

postpartum hospitalization between the groups, and no infants in the vitamin A group had symptoms of hypervitaminosis A, such as excessive crying, raised fontanelle and vomiting. All the infants received a dose of oral polio vaccine (OPV) between 48 and 72 hours after birth. There were no differences between the two groups in OPV seroconversion rates or antibody titers at 6 weeks.[42] Similarly, 1,085 exclusively breastfeeding mothers in Ghana were given 200,000 IU vitamin A or placebo at 3 to 4 weeks postpartum. There were no differences in infant immune response to polio or tetanus vaccination at 6 weeks and 6 months of age.[43]

The infants of 197 mothers in Gambia given either 200,000 or 400,000 IU vitamin A in the first week after delivery showed no signs of adverse reactions to vitamin A during the 12-month follow-up period.[27]

Two hundred forty-five healthy, exclusively breastfeeding mothers in Nanjing, China were randomized to receive a daily vitamin A 1800 IU supplement or placebo for 2 months beginning at 1 to 2 months postpartum. By the end of the 2 month study, infants in both groups had similar rates of febrile illnesses, respiratory tract infections, diarrhea, and eczema, although it was not stated how these data were collected.[23]

## Effects on Lactation and Breastmilk

HIV-infected mothers in Tanzania had a higher rate of severe subclinical mastitis (36%), determined by measuring serial milk electrolyte concentrations, when taking a daily vitamin A supplement during pregnancy and postpartum compared to placebo (23%). Mothers taking a multivitamin without vitamin A also had a higher rate (38%) than placebo, suggesting a vitamin A-independent effect. Given the many other benefits of multivitamin supplementation in this specific patient population, the authors did not recommend avoiding supplementation due to a potential risk of mastitis.[44]

In a Brazilian study, 57 mothers received either 200,000 IU vitamin A or no vitamin A within 2 days after birth. At 24 hours after administration, the average level of alpha-tocopherol (vitamin E) was 16.4% lower in the colostrum of mothers who received in the vitamin A (28 micromoles/L compared to 24.5 micromoles/L), but it was not significantly different at 30 days after administration, at about 6 micromoles/L.[25] The reported vitamin E colostrum levels in this study are within normal limits, thus the small reduction in the vitamin A-supplemented mothers may not be clinically important. A different Brazilian research group conducting the same experiment using a vitamin A supplement with low-dose vitamin E 110 IU added as a preservative found no effect of vitamin A on colostrum alpha-tocopherol.[45]

## Alternate Drugs to Consider

Beta-Carotene

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## Substance Identification

### Substance Name

Vitamin A

### CAS Registry Number

68-26-8; 79-81-2

### Drug Class

Breast Feeding

Lactation

Milk, Human

Vitamins