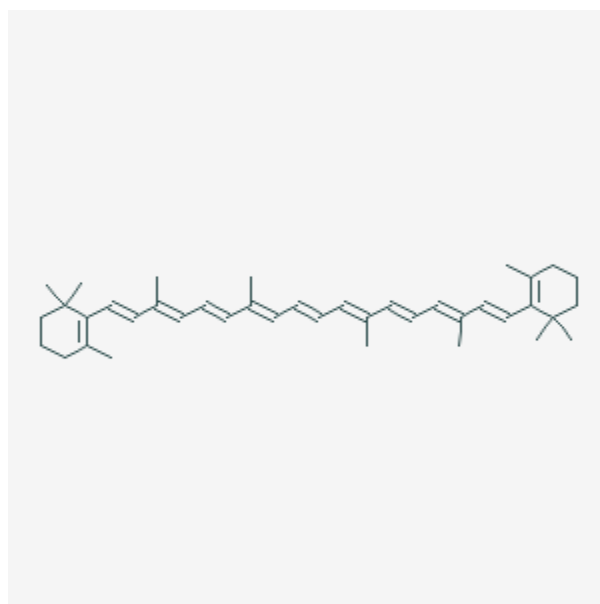




Beta-Carotene

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CASRN: 7235-40-7



Drug Levels and Effects

Summary of Use during Lactation

Beta-carotene is a plant pigment that is converted into vitamin A in the body. Maternal vitamin A requirements are increased during lactation, but there are no specific guidelines for increased beta-carotene intake or indications for high-dose supplementation in nursing mothers. Typical beta-carotene intake in a Western diet is 6 to 8 mg daily. Beta-carotene is a normal component of human colostrum and mature milk, where it contributes to antioxidant defenses in the neonate.[1] Average concentrations are 1.12 mg/L and 230 mcg/L, respectively, in the United States.[2] Beta-carotene supplementation during pregnancy and for 6 months postpartum in nursing mothers with poor diets in a resource-poor setting reduced the number of days of illness in the mothers,[3] but does not reduce infant morbidity or mortality according to another study.[4] The bioavailability of beta-carotene is dependent on the fat content of the meal and the form in which it is administered, with synthetic pharmaceutical forms having the best bioavailability. High-dose beta-carotene

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supplements lead to a slow increase in breastmilk beta-carotene concentrations, with an accumulation half-life of about 9 days. Levels drop towards baseline slowly over several weeks after discontinuation. In general, beta-carotene is well tolerated, although excessive maternal intake of beta-carotene can lead to a harmless, reversible discoloration of the breastfed infant's skin.[5] In HIV-infected women, high-dose beta-carotene plus vitamin A supplementation increases the rate of HIV viral shedding into breastmilk and increases HIV infection in breastfed infants, although the mortality rate over the first 2 years of life is not increased.[6][7] The viral shedding may be a result of an increase in subclinical mastitis caused by beta-carotene.[8] Beta-carotene concentration in breastmilk is not affected by refrigeration, freezing, or low-temperature microwaving. The concentration does decrease when milk passes through a tube feeding system, regardless of light exposure.[9]

Dietary supplements do not require extensive pre-marketing approval from the U.S. Food and Drug Administration. Manufacturers are responsible to ensure the safety, but do not need to *prove* the safety and effectiveness of dietary supplements before they are marketed. Dietary supplements may contain multiple ingredients, and differences are often found between labeled and actual ingredients or their amounts. A manufacturer may contract with an independent organization to verify the quality of a product or its ingredients, but that does *not* certify the safety or effectiveness of a product. Because of the above issues, clinical testing results on one product may not be applicable to other products. More detailed information [about dietary supplements](#) is available elsewhere on the LactMed Web site.

Drug Levels

Maternal Levels. Healthy nursing mothers in the United States were given either 60 mg (n = 6) or 210 mg (n = 6) of beta-carotene as capsules (Hoffmann-La Roche, Inc., Nutley, NJ) as a single dose. Both doses increased breastmilk beta-carotene levels to a similar extent, with peak concentrations of around 1.1 mcg/L of lipid occurring 2 to 3 days after the dose. Mothers with higher baseline beta-carotene levels had higher peak concentrations.[10]

Healthy nursing mothers in the United States were given either 7 doses of a placebo (n = 4) or of an algae-derived beta-carotene supplement containing 64 mg of all-trans beta-carotene and 69 mg 9-cis beta-carotene (Henkel Corp., LaGrange, IL). Foremilk samples of breastmilk were obtained daily for 8 days and again at 1 month after the first dose. All-trans beta-carotene levels in milk increased to about 2.1 mg/L of whole milk after 5 days of supplementation and further increased only slightly by day 8. Levels were still elevated above baseline at 1 month. Milk levels of 9-cis beta-carotene increased steadily from baseline to day 8, with a much lower peak value of about 40 ng/L. The lower value was possibly the result of isomerization of 9-cis beta-carotene to all-trans beta-carotene.[11]

Five healthy exclusively breastfeeding mothers over 1 month postpartum (average 279 days postpartum) in the United States were given 30 mg of beta-carotene as capsules (Hoffmann-La Roche, Inc. Nutley, NJ) daily for 28 days with high-fat yogurt. Milk beta-carotene levels increased an average of 6.4 fold over the 28-day period, with an average maximum concentration of about 200 mcg/L. The accumulation half-life of beta-carotene in milk was 9 days, which was almost twice as long as the accumulation half-life in serum. At one month after the end of supplementation, milk levels remained about double of baseline levels.[12]

In a study in rural Bangladesh, 139 mothers received oral beta-carotene 7.8 mg or placebo once daily for 9 months beginning between 1 and 3 weeks postpartum. Baseline maternal vitamin A status prior to administration was not measured. Average milk retinol levels were similar between the two groups at 3 and 6 months postpartum, but were higher in the beta-carotene group at 9 months (286 mcg/L vs 226 mcg/L). The percentage of women with milk levels <300 mcg/L was also lower (63% vs 80%) at 9 months in the beta-carotene group. The results were the same when the authors controlled for milk fat content.[13]

Twenty-one postpartum women in the United States received either water-dispersible beadlets of beta-carotene in capsules (n = 11), which were assayed to contain 31 to 35 mg of beta-carotene and 1.2 mg of alpha-carotene, or an identical placebo (n = 10) daily for 4 weeks starting on 4 days postpartum. During the 4 weeks of the study, there was no significant change in average breastmilk beta-carotene concentrations, whereas those in the placebo group had a decrease in average beta-carotene milk concentrations which was not statistically significant. Differences between this study and previous studies was suggested to be caused by differences in subjects' milkfat levels which were lower in this study.[14]

A study compared 4 groups of women in West Java, Indonesia who received supplementation during pregnancy until delivery. All groups received 30 mg of iron and 0.4 mg of folic acid daily. Experimental groups received either beta-carotene 4.5 mg daily as a water-soluble granulate, zinc 30 mg daily, beta-carotene 4.5 mg plus zinc 30 mg daily, or only the iron and folic acid as a control group. Milk samples were collected during the first and sixth months postpartum. The milk beta-carotene level was significantly different from the control group only in the 6-month sample of the zinc plus beta-carotene group. The vitamin A status of the mothers and their infants was also better in the group that received beta-carotene and zinc.[15]

A study of 866 HIV-infected women in Tanzania were enrolled in a study to receive 1 of 4 supplements during pregnancy and lactation. Groups received either multivitamins, multivitamins plus vitamin A and beta-carotene, vitamin A and beta-carotene alone, or placebo daily. The beta-carotene dose was 30 mg. At 24 months of age, the multivitamin-supplemented group's infants had significantly better growth parameters than the other groups. [16]

A study of HIV-infected women in Tanzania were enrolled in a study to receive 1 of 4 supplements during pregnancy and lactation. Groups receive either multivitamins (thiamine, riboflavin, vitamin B6, niacin, vitamin B12, vitamin C, vitamin E, and folic acid), multivitamins plus vitamin A and beta-carotene, vitamin A and beta-carotene alone, or placebo daily. The beta-carotene dose was 30 mg. Breastmilk samples were collected at delivery and at 3-month intervals thereafter. Average breastmilk beta-carotene concentrations in the beta-carotene supplemented groups were consistently about 10-fold higher than in the groups that received no beta-carotene at any time up to 1 year of age.[17]

Twelve women were given carrot paste and 14 were given tomato paste with a high-fat meal once daily for 3 days. The carrot supplement contained 15 mg of all-trans beta-carotene and the tomato supplement contained 15 mg of all-trans lycopene. Breastmilk beta-carotene levels nearly doubled after 3 days of supplementation, whereas lycopene levels increased by about 15% one day after the 3 days of supplementation.[18]

Infant Levels. Relevant published information was not found as of the revision date.

Effects in Breastfed Infants

A nursing mother was eating 2 to 3 pounds of carrots a week as raw and cooked carrots. The mother's skin was yellow in color, but her sclera were clear. At 2 months of age, her breastfed infant was diagnosed as having jaundice because of a yellow coloration of the skin. Breastfeeding was discontinued and the infant's skin returned to a normal color. The mother continued her diet and examination of the maternal serum found elevated levels of beta-carotene which was probably the cause of her infant's skin discoloration.[5]

HIV-infected women in Tanzania received 1 of 4 supplements during pregnancy and lactation in a series of studies. Groups received either multivitamins (thiamine, riboflavin, vitamin B6, niacin, vitamin B12, vitamin C, vitamin E, and folic acid), multivitamins plus vitamin A and beta-carotene, vitamin A and beta-carotene alone, or placebo daily. The beta-carotene dose was 30 mg. At 24 months of age, the multivitamin-supplemented group's infants had significantly better growth parameters than the other groups.[16] One study found that the infants of mothers supplemented with vitamin A and beta-carotene had a higher rate of HIV transmission than those supplemented with multivitamins alone or placebo.[6] After 6 months postpartum, women who received

vitamin A plus beta-carotene had greater shedding of the HIV virus into breastmilk than women who had not; multivitamins without vitamin A and beta-carotene did not increase viral shedding.[6] Beta-carotene appeared to have a shedding effect that was independent of vitamin A.[7] One possible explanation comes from another similar study in which those who received vitamin A plus beta-carotene alone had a 45% increased risk of severe subclinical mastitis and those who received multivitamins plus vitamin A and beta-carotene had a 29% increased risk of severe subclinical mastitis.[8]

Effects on Lactation and Breastmilk

Relevant published information was not found as of the revision date.

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Substance Identification

Substance Name

Beta-Carotene

CAS Registry Number

7235-40-7

Drug Class

Breast Feeding

Lactation

Complementary Therapies

Carotenoids

Food

Vitamins