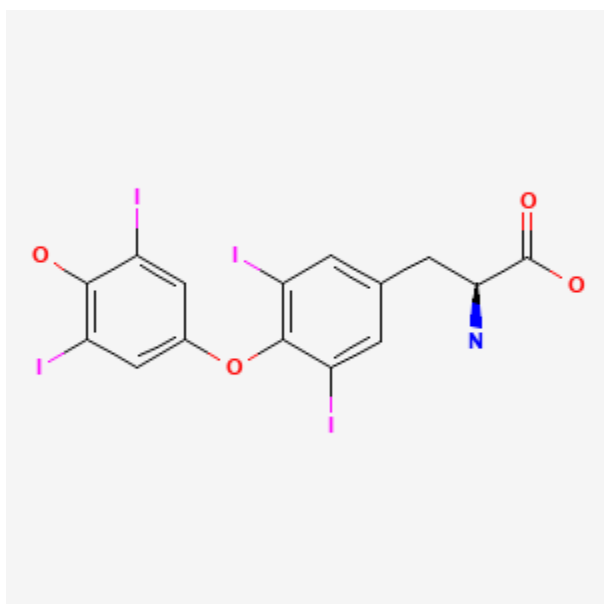




## Levothyroxine

Revised: September 15, 2023.

CASRN: 51-48-9



## Drug Levels and Effects

### Summary of Use during Lactation

Levothyroxine (T4) is a normal component of human milk. Limited data on exogenous replacement doses of levothyroxine during breastfeeding indicate no adverse effects in infants. The American Thyroid Association recommends that subclinical and overt hypothyroidism should be treated with levothyroxine in lactating women seeking to breastfeed.[1] Adequate levothyroxine treatment during lactation may normalize milk production in hypothyroid lactating mothers with low milk supply. Levothyroxine dosage requirement may be increased in the postpartum period compared to prepregnancy requirements in patients with Hashimoto's thyroiditis.[2]

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## Drug Levels

Levothyroxine is a normal component of human milk. Although somewhat controversial, it appears that levothyroxine passes into milk poorly.[3-7] Average levothyroxine levels reportedly range from 0 to 77 mcg/L.[8] In one study, term and preterm breast milk samples were collected monthly for 6 months from mothers of term (n = 16) or preterm (n = 15) infants. Term milk contained higher average amounts of thyroxine 11,245.5 nmol/L (8738 mcg/L) than preterm milk. 671.6 nmol/L (522 mcg/L). In the milk of preterm mothers, average thyroxine levels were 842.2 nmol/L (654 mcg/L) in the first two months of lactation compared to 595.7 nmol/L (463 mcg/L) in the 3rd through 6th month of lactation.[9]

*Maternal Levels.* In a study of 56 mothers with thyroid disorders, 50 had hypothyroidism and were being treated with levothyroxine; 5 mothers had controlled hyperthyroidism with no medications and 1 had hyperthyroidism treated with a medication. Milk levels of thyroid hormones were free T4 4.5 ng/L, total T4 29.6 mcg/L, free T3 2.3 ng/L and total T3 0.35 mcg/L. The average milk to serum level ratios over the period were free T4 0.32 and total T4 0.3. Levels of free and total T3 and total T4 in milk were positively correlated with their respective plasma levels.[10]

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

## Effects in Breastfed Infants

Effects of exogenous thyroid hormone administration to mothers on their infant have not been reported. One case of apparent mitigation of cretinism in hypothyroid infants by breastfeeding has been reported, but the amounts of thyroid hormones in milk are not optimal, and this result has been disputed.[11,12] The thyroid hormone content of human milk from the mothers of very preterm infants appears not to be sufficient to affect the infants' thyroid status.[13] The amounts of thyroid hormones in milk are apparently not sufficient to interfere with diagnosis of hypothyroidism.[14]

In a telephone follow-up study, 5 nursing mothers reported taking levothyroxine (dosage unspecified). The mothers reported no adverse reactions in their infants.[15]

One mother who had undergone a thyroidectomy was taking levothyroxine 100 mcg daily as well as calcium carbonate and calcitriol. Her breastfed infant was reportedly "thriving" at 3 months of age.[16]

A woman with propionic acidemia took levothyroxine 50 mcg daily as well as biotin, carnitine, and various amino acids while exclusively breastfeeding her infant for 2 months and nonexclusively for 10 months. At that time, the infant had normal growth and development.[17]

## Effects on Lactation and Breastmilk

Adequate thyroid hormone serum levels are required for normal lactation. Replacing deficient thyroid levels should improve milk production caused by hypothyroidism. Supraphysiologic doses would not be expected to further improve lactation.

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## Substance Identification

### Substance Name

Levothyroxine

### CAS Registry Number

51-48-9

### Drug Class

Breast Feeding

Lactation

Milk, Human

Thyroid Hormones