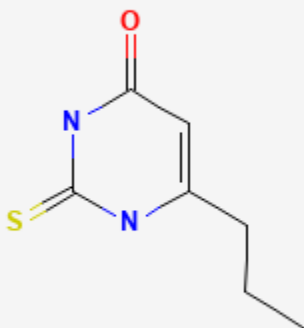




Propylthiouracil

Revised: July 15, 2024.

CASRN: 51-52-5



Drug Levels and Effects

Summary of Use during Lactation

Propylthiouracil (PTU) had been considered the antithyroid drug of choice during lactation;^[1,2] however, findings that the rates of liver injury higher with PTU than with methimazole has altered this judgement. Some experts now recommend that methimazole should be considered the antithyroid drug of choice in nursing mothers.^[3-5] No cases of PTU-induced liver damage have been reported in breastfed infants and it is unknown if the small amounts of the drug in breastmilk can cause liver damage. The drug or breastfeeding should be discontinued if liver toxicity is suspected. Dosages of PTU should be limited to 450 mg daily during breastfeeding.^[6]

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The American Thyroid Association recommends only monitoring infants for appropriate growth and development during routine pediatric health and wellness evaluations and routine assessment of serum thyroid function in the child is not recommended.[6] Rare idiosyncratic reactions (e.g., agranulocytosis) might occur, and the infant should be watched for signs of infection. Monitoring of the infant's complete blood count and differential is advisable if there is a suspicion of a drug-induced blood dyscrasia.

Drug Levels

Maternal Levels. A woman (time postpartum not stated) given a single dose of 100 mg of propylthiouracil (PTU) excreted a total of 0.077% of the dose in her breastmilk in 24 hours.[7]

After a single oral dose of 400 mg of propylthiouracil (PTU) in 9 women who were 1 to 9 months postpartum, peak milk levels averaging 0.7 mg/L were reached 1.5 hours after the dose. The authors estimated that the infant of a mother taking 200 mg 3 times a day would receive no more than 462 mcg daily or a maximum of 0.025% (range 0.07 to 0.077%) of the maternal dosage.[8]

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

Effects in Breastfed Infants

A mother was taking oral propylthiouracil 100 mg daily during pregnancy and 125 mg daily after delivery. In her infant, serum thyroxine (T4) concentration dropped slightly below the lower limit of normal on day 4 of life, but both T4 and thyrotropin (TSH) concentrations were normal on day 19 with continued maternal PTU therapy.[9] The drop in T4 was possibly due to propylthiouracil in breastmilk, but more likely from PTU received transplacentally.

An infant whose mother was taking propylthiouracil 200 to 300 mg daily was followed for 5 months and found to have normal thyroid function tests.[8]

A mother took PTU in a starting dose of 100 mg 3 times daily that was tapered to 50 mg twice daily over a period of 6 months. Her breastfed infant had normal thyroid function tests during this period at the ages of 9 to 13 months of age.[10]

Eight mothers taking PTU during pregnancy and doses of 50 to 300 mg daily after delivery exclusively or nearly exclusively breastfed their infants. The infants all had slightly low free T4 levels at birth and TSH levels were above normal in 7 of the 8, indicating that they had been affected by PTU in utero. All of their infants had normal free T4 and TSH levels when measured between 18 days and 8 months of age and none had any adverse effects reported from PTU in milk.[11]

The mothers of 11 fully breastfed infants were taking 300 to 750 mg daily of PTU starting at various times between delivery and 11 months postpartum. One infant had slightly elevated TSH level at 19 weeks of age when his mother was taking PTU 450 mg daily. Two other infants had elevated TSH levels at birth. TSH normalized in both infants with maternal PTU doses of 600 mg daily in one and a dose starting at 300 mg daily at term and increasing to 600 mg daily in the other.[12]

Two other infants were reported to be hypothyroid at birth, but to have normal thyroid function at 1 month of age despite maternal PTU therapy during breastfeeding.[13]

Effects on Lactation and Breastmilk

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

References

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Substance Identification

Substance Name

Propylthiouracil

CAS Registry Number

51-52-5

Drug Class

Breast Feeding

Lactation

Milk, Human

Antithyroid Agents

Thionamides