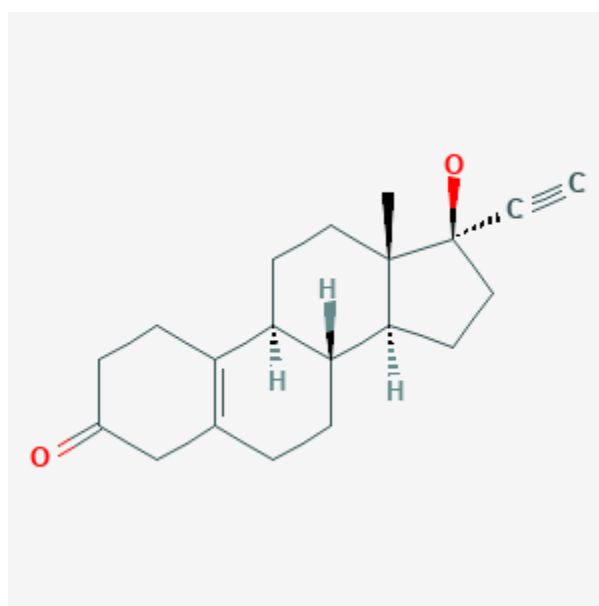




## Norethynodrel

Revised: October 31, 2018.

CASRN: 68-23-5



## Drug Levels and Effects

### Summary of Use during Lactation

Norethynodrel is only available in the United States in combination oral contraceptive products. Based on the available evidence, expert opinion holds that nonhormonal methods are preferred during breastfeeding and progestin-only contraceptive are preferred over combined oral contraceptives in breastfeeding women, especially during the first 4 weeks postpartum. For further information, consult the record entitled, "Contraceptives, Oral, Combined."

### Drug Levels

Norethynodrel is a prodrug that is rapidly converted to norethindrone in the body.[1]

*Maternal Levels.* In one old study using a nonspecific radiolabeling assay technique, 2 women were found to excrete 0.0044% and 0.13% of an administered dose (not weight-adjusted) of norethynodrel into breastmilk.[2]

In another study using radioactive labeled norethynodrel, 4 women who were between days 4 and 6 postpartum excreted an average of 1.1% (range 0.45 to 1.52%) of a dose (not weight-adjusted) into breastmilk.[3]

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

## Effects in Breastfed Infants

Abnormal breast enlargement was reported in a 3-week-old male breastfed infant whose mother was taking an oral contraceptive containing norethynodrel 25 mg and mestranol 100 mcg.[4] The contraceptive was the probable cause of breast enlargement, but most likely the estrogen component mestranol rather than norethynodrel caused the effect.

## Effects on Lactation and Breastmilk

Relevant published information was not found as of the revision date. However, progestins such as norethynodrel are not considered to suppress lactation.

A study analyzed data from a prospective cohort study of U.S. women from May 2005 through June 2007. Women were followed from the third trimester of pregnancy throughout the first year postpartum. Data from the subset of women who intended to breastfeed for 3 months or longer postpartum during their third trimester of pregnancy and who were using a contraceptive at 3 months postpartum were analyzed (n = 1349). Women who intended to breastfeed for at least 4 months and were taking a progestin-only oral contraceptive, such as norethynodrel, were 3.15 times more likely to be breastfeeding (exclusive or nonexclusive) at 4 months than women who used a nonhormonal contraceptive. Women who said they would breastfeed for 3 to 4 months had 4-month breastfeeding rates equivalent to those using a nonhormonal contraceptive. These rates were much higher than those of women who were taking an estrogen-containing, combined oral contraceptive.[5]

## Alternate Drugs to Consider

Etonogestrel, Intrauterine Copper Contraceptive, Oral Levonorgestrel, Intrauterine Levonorgestrel, Levonorgestrel Implant, Medroxyprogesterone Acetate, Norethindrone, Progesterone

## References

1. Orme ML, Back DJ, Breckenridge AM. Clinical pharmacokinetics of oral contraceptive steroids. Clin Pharmacokinet. 1983;8:95-136. PubMed PMID: 6342899.
2. Pincus G, Bialy G et al. Radioactivity in the milk of subjects receiving radioactive 19-norsteroids. Nature. 1966;212:924-5. PubMed PMID: 6012386.
3. Laumas KR, Malkani PK et al. Radioactivity in the breast milk of lactating women after oral administration of 3H-norethynodrel. Am J Obstet Gynecol. 1967;98:411-3. PubMed PMID: 5630224.
4. Curtis EM. Oral-contraceptive feminization of a normal male infant. Obstet Gynecol. 1964;23:295-6. PubMed PMID: 14117345.
5. Goulding AN, Wouk K, Stuebe AM. Contraception and breastfeeding at 4 months postpartum among women intending to breastfeed. Breastfeed Med. 2018;13:75-80. PubMed PMID: 29091478.

## Substance Identification

### Substance Name

Norethynodrel

## **CAS Registry Number**

68-23-5

## **Drug Class**

Breast Feeding

Lactation

Contraceptive Agents, Female

Contraceptives, Oral, Synthetic