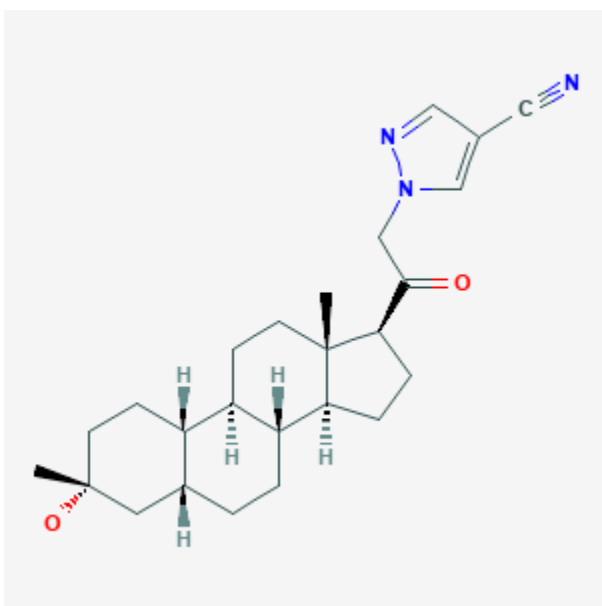




## Zuranolone

Revised: June 15, 2024.

CASRN: 1632051-40-1



## Drug Levels and Effects

### Summary of Use during Lactation

Because of the low amounts of zuranolone in milk, it would not be expected to cause any adverse effects in breastfed infants. If zuranolone is required by the mother, it is not a reason to discontinue breastfeeding. Until more data are available, zuranolone should be used with careful infant monitoring for excessive sedation during breastfeeding, especially with higher dosages and in newborn and preterm infants.

### Drug Levels

*Maternal Levels.* A manufacturer-sponsored study was conducted in 14 healthy lactating women who were 12 or more weeks postpartum and treated with oral administration of 30 mg of zuranolone daily at home for 14 days.

**Disclaimer:** Information presented in this database is not meant as a substitute for professional judgment. You should consult your healthcare provider for breastfeeding advice related to your particular situation. The U.S. government does not warrant or assume any liability or responsibility for the accuracy or completeness of the information on this Site.

**Attribution Statement:** LactMed is a registered trademark of the U.S. Department of Health and Human Services.

On day 5 of treatment, they came to the study site where they received their 8 pm dose after a fat-containing meal. Participants collected milk samples at variable times over 11 days after the start of therapy. Milk concentration values were used along with blood samples from day 5 in a population pharmacokinetic model (NONMEM) to simulate the mean breastmilk levels in 1000 female patients. The daily infant dose via milk was estimated to be 0.00125 mg/kg on day 5 of therapy, resulting in a mean weight-adjusted relative infant dose of 0.74% using the standard of 150 mL/kg of milk per day.[1] Product information further states that the concentrations of zuranolone in breastmilk were below the level of quantification limit by 4 to 6 days after the last dose.

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

## Effects in Breastfed Infants

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

## Effects on Lactation and Breastmilk

In a manufacturer-sponsored study, 14 healthy lactating women who were 12 or more weeks postpartum and treated with oral administration of 30 mg of zuranolone daily for 14 days collected milk samples from 3 days before to day 5 of treatment. There was a mean decrease of 41.2 mL or 8.3% in milk volume collected over days 3 to 5 of treatment compared with pretreatment baseline.[1] However, this decrease could be an artifact of the study design, because participants were told to stop breastfeeding and pump their milk during the study. Other factors could have been at play, also.

## Alternate Drugs to Consider

Brexanolone, Nortriptyline, Paroxetine, Sertraline

## References

1. Deligiannidis KM, Bullock A, Nandy I, et al. Zuranolone concentrations in the breast milk of healthy, lactating individuals: Results from a phase 1 open-label study. *J Clin Psychopharmacol* 2024. PubMed PMID: 38739007.

## Substance Identification

### Substance Name

Zuranolone

### CAS Registry Number

1632051-40-1

### Drug Class

Breast Feeding

Lactation

Milk, Human

Antidepressants

Antidepressive Agents

GABA Agents

Hormones

Progesterone Congeners