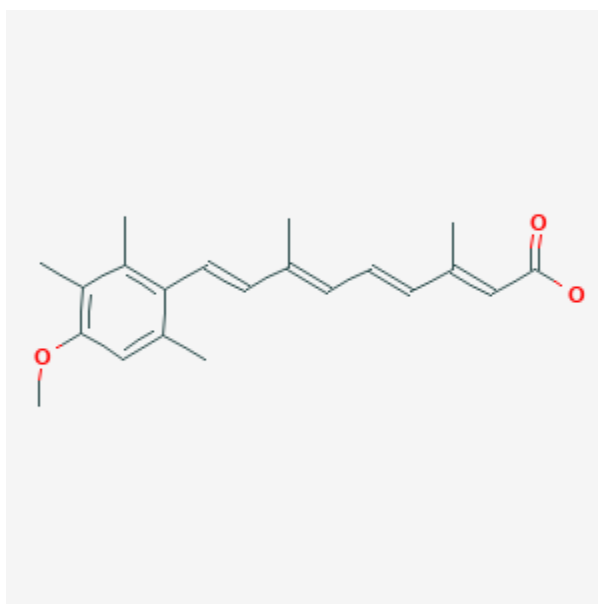




## Acitretin

Revised: June 30, 2019.

CASRN: 55079-83-9



## Drug Levels and Effects

### Summary of Use during Lactation

A maternal acitretin dose of 0.65 mg/kg daily produced low levels in milk in one woman. Because there is no published experience with use of acitretin during breastfeeding, opinions vary on the advisability of breastfeeding during acitretin therapy.[1][2][3] Various topical agents that are less likely to be absorbed by the mother may be preferred during breastfeeding, especially while nursing a newborn or preterm infant. Only water-miscible cream or gel products should be applied to the breast because ointments may expose the infant to high levels of mineral paraffins via licking.[4]

### Drug Levels

*Maternal Levels.* A woman who was 8 months postpartum discontinued breastfeeding and began acitretin 40 mg (0.65 mg/kg) once daily by mouth after breakfast. Milk was collected before starting the drug and then twice

daily for 9 days. Acitretin and its 13-cis-metabolite were detected in milk 12 hours after the first dose and levels gradually increased over 4 to 5 days to steady-state levels between 30 and 40 mcg/L that did not fluctuate markedly during the day. Acitretin was the main component found in milk 10 to 12 hours after a dose while the metabolite was the primary component in milk 22 to 24 hours after the previous dose.[1] Assuming an average milk level of 35 mcg/L, an exclusively breastfed infant would receive an estimated 0.8% of the maternal weight-adjusted dosage as acitretin and its metabolite.

*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

A review of adverse reaction reports on retinoids causing a breast reaction submitted to a French pharmacovigilance center found 8 cases of gynecomastia associated with acitretin use.[5]

## References

1. Rollman O, Pihl-Lundin I. Acitretin excretion into human breast milk. *Acta Derm Venereol.* 1990;70:487-90. PubMed PMID: 1981420.
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4. Noti A, Grob K, Biedermann M et al. Exposure of babies to C(15)-C(45) mineral paraffins from human milk and breast salves. *Regul Toxicol Pharmacol.* 2003;38:317-25. PubMed PMID: 14623482.
5. Atzenhoffer M, Pierre S, Bellet F et al. Gynecomastia and galactorrhea: Unlabeled adverse drug reactions of retinoids used in dermatology. *Drug Safety.* 2018;41:1198-9. Abstract DOI: [10.1007/s40264-018-0719-2](https://doi.org/10.1007/s40264-018-0719-2).

## Substance Identification

### Substance Name

Acitretin

### CAS Registry Number

55079-83-9

### Drug Class

Breast Feeding

Lactation

Keratolytic Agents

Retinoids