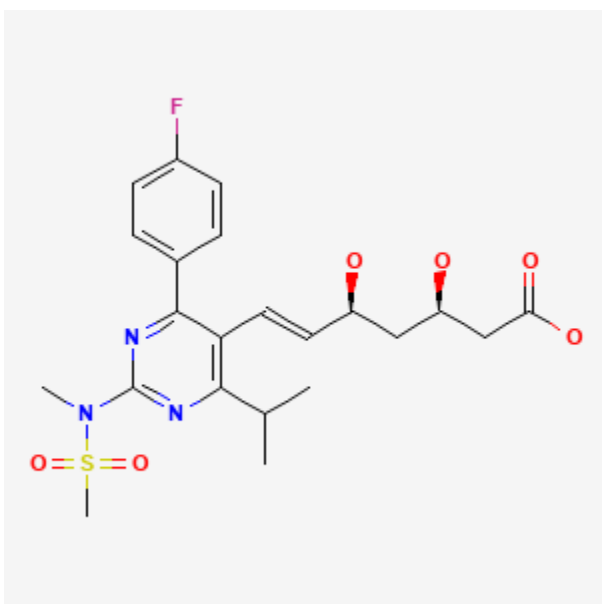




Rosuvastatin

Revised: September 20, 2021.

CASRN: 287714-41-4



Drug Levels and Effects

Summary of Use during Lactation

Levels of rosuvastatin in milk are low, but no relevant published information exists with its use during breastfeeding. The consensus opinion is that women taking a statin should not breastfeed because of a concern with disruption of infant lipid metabolism. However, others have argued that children homozygous for familial hypercholesterolemia are treated with statins beginning at 1 year of age, that statins have low oral bioavailability, and risks to the breastfed infant are low, especially with rosuvastatin and pravastatin.[1] Until more data become available, an alternate drug may be preferred, especially while nursing a newborn or preterm infant.

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.

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Drug Levels

Maternal Levels. A woman with familial hypercholesterolemia was started on rosuvastatin 40 mg daily on day 33 postpartum. On one unspecified day after beginning rosuvastatin, the breastmilk rosuvastatin concentration was about 22 mcg/L at 21 hours after the previous dose. One hour after the dose, the breastmilk concentration was 15.2 mcg/L, and 7 hours after the dose, the breastmilk concentration was 29.4 mcg/L. Breastmilk concentrations were also measured on day 4 at 3 hours after the dose, day 24 at 3.8 hours after the dose, and on day 80 at 21 hours after the dose. All of these concentrations were in the range of 21 to 22 mcg/L.[2]

Rosuvastatin was being initiated in a nursing mother who was 13 months postpartum and weaning her infant. She began with a dose of 20 mg daily at bedtime. After 5 days of therapy, she donated 8 milk samples over a 24-hour period. The trough milk concentration was 16.6 mcg/L at 5 hours after the dose and remained relatively constant until about 15 hours after the dose. The peak milk concentration of 58.6 mcg/L occurred 17 hours after the dose. The authors calculated a daily infant dosage of 4.63 mcg/kg, which corresponded to a weight-adjusted 1.5% of the maternal dose.[3]

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 possible case of rosuvastatin-induced gynecomastia has been reported. Serum prolactin was not measured.[4]

Alternate Drugs to Consider

Cholestyramine, Colesevelam, Colestipol

References

1. Holmsen ST, Bakkebo T, Seferowicz M, et al. Statins and breastfeeding in familial hypercholesterolaemia. *Tidsskr Nor Laegeforen.* 2017;137:686–7. PubMed PMID: 28551957.
2. Schutte AE, Symington EA, du Preez JL. Rosuvastatin is transferred into human breast milk: A case report. *Am J Med.* 2013;126:e7–8. PubMed PMID: 23968910.
3. Lwin EMP, Leggett C, Ritchie U, et al. Transfer of rosuvastatin into breast milk: Liquid chromatography-mass spectrometry methodology and clinical recommendations. *Drug Des Devel Ther.* 2018;12:3645–51. PubMed PMID: 30464396.
4. Oteri A, Catania MA, Travaglini R, et al. Gynecomastia possibly induced by rosuvastatin. *Pharmacotherapy.* 2008;28:549–51. PubMed PMID: 18363539.

Substance Identification

Substance Name

Rosuvastatin

CAS Registry Number

287714-41-4

Drug Class

Breast Feeding

Lactation

Anticholesteremic Agents

Antilipemic Agents

Hydroxymethylglutaryl-CoA Reductase Inhibitors