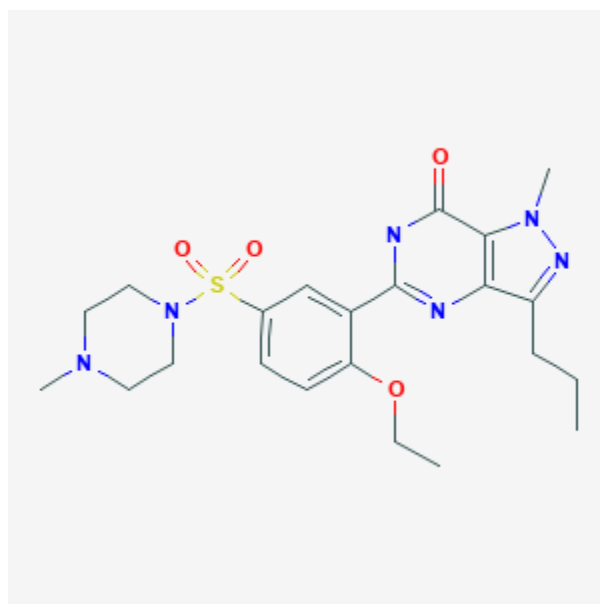




Sildenafil

Revised: December 3, 2018.

CASRN: 139755-83-2



Drug Levels and Effects

Summary of Use during Lactation

Limited data indicate that sildenafil and its active metabolite in breastmilk are poorly excreted into breastmilk. Amounts ingested by the infant are small and would not be expected to cause any adverse effects in breastfed infants.

Drug Levels

Sildenafil is metabolized by CYP3A4 and 2C9 to the active metabolite, desmethylsildenafil, which has about one-half the potency of sildenafil.

Maternal Levels. A breastfeeding woman receiving sildenafil 20 mg for pulmonary hypertension. Breastmilk samples were taken 8 hours after a dose, followed by another dose 11 hours after the first. Then further milk

samples were obtained about 3.5 and 6 hours after the second dose. The highest sildenafil and desmethylsildenafil milk levels of 4.49 mcg/L and 1.82 mcg/L, respectively, were in the second sample. Concentrations of sildenafil at the first and last samples were 1.64 and 1.67 mcg/L. Concentrations of desmethylsildenafil at the first and last sampling times were 1.18 and 1.73 mcg/L.[1]

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

Effects in Breastfed Infants

A 23-year-old woman with congenital heart disease and pulmonary hypertension was treated during pregnancy with sildenafil and bosentan in unspecified dosages. These drugs and warfarin were continued postpartum. Her infant was delivered at 30 weeks by cesarean section and weighed 1.41 kg at birth. She nursed the infant in the neonatal intensive care unit for 11 weeks "with good outcome" according to the authors, but the infant died at 26 weeks from a respiratory syncytial virus infection.[2]

Effects on Lactation and Breastmilk

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

References

1. Wollein U, Schech B, Hardt J et al. Determination and quantitation of sildenafil and its major metabolite in the breast milk of a lactating woman. *J Pharm Biomed Anal.* 2015;120:100-5. PubMed PMID: 26717019.
2. Molelekwa V, Akhter P, McKenna P et al. Eisenmenger's syndrome in a 27 week pregnancy--management with bosentan and sildenafil. *Ir Med J.* 2005;98:87-8. PubMed PMID: 15869069.

Substance Identification

Substance Name

Sildenafil

CAS Registry Number

139755-83-2

Drug Class

Breast Feeding

Lactation

Phosphodiesterase 5 Inhibitors

Vasodilator Agents