

Amlodipine (Norvasc®)

Selected References:

- Ahn HK, et al. 2007. Exposure to amlodipine in the first trimester of pregnancy and during breastfeeding. *Hypertension in pregnancy*, 26(2):179-187.
- Aoki H, et al. 2018. Low Levels of Amlodipine in Breast Milk and Plasma. *Breastfeeding medicine*, 13(9):622-626.
- Centers for Disease Control and Prevention. (2024). Health and economic benefits of high blood pressure interventions. Retrieved August 2024 from <https://www.cdc.gov/nccdphp/priorities/high-blood-pressure.html>.
- Faham DE, et al. 2019. Can Amlodipine Improve the Pre-ovulatory Follicle Blood Flow in Women with Polycystic Ovarian Syndrome?. *Journal of reproduction & infertility*, 20(2):89-94.
- Ishikawa T, et al. 2023. Risk of major congenital malformations associated with first-trimester antihypertensives, including amlodipine and methyldopa: A large claims database study 2010-2019. *Pregnancy hypertension*, 31:73-83.
- Magee LA, et al. 1996. The safety of calcium channel blockers in human pregnancy: a prospective, multicenter cohort study. *Am J Obstet Gynecol*, 174(3):823-828.
- Mito AA, et al. 2019. Safety of Amlodipine in Early Pregnancy. *Journal of the American Heart Association*, 8(15):1-7.
- Morgan JL, et al. 2018. Pharmacokinetics of amlodipine besylate at delivery and during lactation. *Pregnancy hypertension*, 11:77-80.
- Naito T, et al. 2015. Amlodipine passage into breast milk in lactating women with pregnancy-induced hypertension and its estimation of infant risk for breastfeeding. *Journal of human lactation*, 31(2):301-306.
- Rosbotham JL, et al. 1998. Painful subcutaneous fat necrosis of the newborn associated with intra-partum use of a calcium channel blocker. *Clinical and experimental dermatology*. 23(1):19-21.
- Szucs KA, et al. 2010. Maternal membranous glomerulonephritis and successful exclusive breastfeeding. *Breastfeeding Medicine*, 5(3):123-126.
- S. Food and Drug Administration. (2011). Norvasc (Amlodipine besylate) tablets label. Retrieved August 2024 from https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/019787s047lbl.pdf.
- Vigil-De Gracia P, et al. 2014. Management of chronic hypertension during pregnancy with furosemide, amlodipine or aspirin: a pilot clinical trial. *The journal of maternal-fetal & neonatal medicine: the official journal of the European Association of Perinatal Medicine, the Federation of Asia and Oceania Perinatal Societies, the International Society of Perinatal Obstetricians*, 27(13): 1291-1294.
- Yin J, et al. 2022. Nifedipine or amlodipine? The choice for hypertension during pregnancy: a systematic review and meta-analysis. *Archives of Gynecology and Obstetrics*, 306(6):1891-1900.

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Amlodipine (Norvasc®)

Selected References:

- Auffret M, et al. 2016. Misoprostol exposure during the first trimester of pregnancy: Is the malformation risk varying depending on the indication? *Eur J Obstet Gynecol Reprod Biol*, 207:188-192.
- Baev OR, et al. 2017. Outcomes of mifepristone usage for cervical ripening and induction of labour in full-term pregnancy. Randomized controlled trial. *Eur J Obstet Gynecol Reprod Biol*, 217:144-149.
- Brown A, et al. 2002. Daily low dose mifepristone has contraceptive potential by suppressing ovulation and menstruation: a double-blind randomised controlled trial of 2 and 5 mg per day for 120 days. *J Clin Endocrinol Metab*, 87:63-70.
- Bos-Thompson MA, et al. 2008. Mobius syndrome in a neonate after mifepristone and misoprostol elective abortion failure. *Ann Pharmacother*, 42(6):888-892.
- Chen A, et al. 2004. Mifepristone-induced early abortion and outcome of subsequent wanted pregnancy. *Am J Epidemiol*, 160(2):110-117.
- Gary MM, Harrison DJ. 2006. Analysis of severe adverse events related to the use of mifepristone as an abortifacient. *Ann Pharmacother*, 40:191-197.
- Glasier A, et al. 1992. Mifepristone (RU 486) compared with high-dose estrogen and progestogen for emergency postcoital contraception. *N Engl J Med*, 327:1041-1044.
- Juneja SC, Dodson MG. 1990. In vitro effect of RU 486 on sperm-egg interaction in mice. *Am J Obstet Gynecol*, 163:216-221.
- Lakha F, et al. 2007. A novel estrogen-free oral contraceptive pill for women: multicentre, double-blind, randomized controlled trial of mifepristone and progestogen-only pill (levonorgestrel). *Hum Reprod*, 22(9):2428-2436.
- Liao H, et al. 2011. Repeated medical abortions and the risk of preterm birth in the subsequent pregnancy. *Arch Gynecol Obstet*, 284(3):579-586.
- Lim BH, et al. 1990. Normal development after exposure to mifepristone in early pregnancy. *Lancet*, 336:257-258.
- Mifepristone Drug Label. 2023. Available at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=b63fad9b-7f12-4400-9019-b0586054e534>.
- Peyron R, et al. 1993. Early termination of pregnancy with mifepristone (RU 486) and the orally active prostaglandin misoprostol. *N Engl J Med*, 328:1509-1513.
- Pons JC, et al. 1991. Development after exposure to mifepristone in early pregnancy. *Lancet*; 338:763.
- Saav I, et al. 2010. Medical abortion in lactating women—low levels of mifepristone in breast milk. *Acta Obstet Gynecol Scand*, 89(5):618-622.
- Sanchez-Criado JE, et al. 1990. A possible dual mechanism of the anovulatory action of antiprogesterone RU486 in the rat. *Biol Reprod*, 42:877-886.

- Shoupe D, et al. 1987. Effects of the antiprogesterone RU 486 in normal women. II. Administration in the late follicular phase. Am J Obstet Gynecol, 157:1421-1426.
- Sitruk-Ware R, Davey A, Sakiz E. 1998. Fetal malformations and failed medical termination of pregnancy. Lancet, 352:323.
- Swahn ML, et al. 1996. Contraception with anti-progesterone. Baillieres Clin Obstet Gynaecol, 10(1):43-53.
- Task force on postovulatory methods of fertility regulation. 1999. Comparison of three single doses of mifepristone as emergency contraception: a randomised trial. Lancet 353:607-702.
- van der Schoot P, et al. 1987. Effects of the progesterone antagonist RU486 on ovarian activity in the rat. Endocrinology, 121:1375-1382.
- Wolf JP, et al. 1990. Tolerance of perinidatory primate embryos to RU 486 exposure in vitro and in vivo. Contraception, 41:85-92.
- Yang YQ, Wu JT. 1990. RU 486 interferes with egg transport and retards the in vivo and in vitro development of mouse embryos. Contraception, 41:551-556.
- Zhu QX, et al. 2009. Mifepristone-induced abortion and placental complications in subsequent pregnancy. Hum Reprod, 24(2):315-319.

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Selected References:

- American College of Obstetricians and Gynecologists (ACOG). 2022/Apr. Preeclampsia and High Blood Pressure during Pregnancy.
<https://www.acog.org/womens-health/faqs/preeclampsia-and-high-blood-pressure-during-pregnancy>
- Anderson PO, et al 2020. Drug treatment of Raynaud's phenomenon of the nipple. Breastfeed Med 15:686-8.
- Benoff S, et al. 1994. The effect of calcium ion channel blockers on sperm fertilization potential. Fertil Steril

62:606-17.

- Bortolus R, et al. 2000. Nifedipine administered in pregnancy: Effect on the development of children at 18 months. BJOG 107:792-794.
- Davis RL, et al 2011. Risks of congenital malformations and perinatal events among infants exposed to calcium channel and beta-blockers during pregnancy. Pharmacoevidenciol Drug Saf 20:13-145.
- Dublin S, et al. 2022. Maternal and neonatal outcomes of antihypertensive treatment in pregnancy: a retrospective cohort study. PLoS One 17(5):e0268284
- George R, et. 2022. Comparative efficacy and safety of oral nifedipine with other antihypertensive medications in the management of hypertensive disorders of pregnancy: a systematic review and meta-analysis of randomized controlled trials. J Hypertens 40(10):1876-1886.
- Houtzager BA, et al. 2006. Long-term follow up of children exposed in utero to nifedipine or ritodrine for the management of preterm labour. BJOG. 2006 Mar; 113(3):324-31.
- Magee LA, et al. 1996. The safety of calcium channel blockers in human pregnancy: A prospective, multicenter cohort study. Am J Obstet Gynecol 174:823-828.
- Malfará BN, et al. 2019. ABCG2 c.421C>A polymorphism alters nifedipine transport to breast milk in hypertensive breastfeeding women. Reprod Toxicol 85:1-5.
- Penny WJ, Lewis MJ. 1989. Nifedipine is excreted in human milk. Eur J Clin Pharmacol. 36(4):427-8.
- Tabacova SA, et al. 2002. Developmental abnormalities reported to FDA in association with nifedipine treatment in pregnancy. Teratology; 65:368.
- Taddio A, et al 1996. Is nifedipine use during labor and breast-feeding safe for the neonate? Clin Investig Med 19:S11. Abstract.
- Weber-Schoendorfer C, et al. 2008. The safety of calcium channel blockers during pregnancy: a prospective, multicenter, observational study. Reprod Toxicol 26(1): 24-30.
- Wu M, et al 2012. Raynaud's phenomenon of the nipple. Obstet Gynecol. 119(2 Pt 2):447-9.

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- Agrawal M, et al. 2022. Antithyroid drug therapy in pregnancy and risk of congenital anomalies: Systematic review and meta-analysis. *Clinical endocrinology*, 96(6):857-868.
- Akmal A, Kung J. 2014. Propylthiouracil, and methimazole, and carbimazole-related hepatotoxicity. *Expert Opin Drug Saf*, 13(10):1397-1406.
- Alexander EK, et al. 2017. 2017 Guidelines of the American Thyroid Association for the Diagnosis and Management of Thyroid Disease During Pregnancy and the Postpartum. *Thyroid: official journal of the American Thyroid Association*, 27(3):315-389.
- American College of Obstetricians and Gynecology. 2020. Thyroid disease in pregnancy. *ACOG Practice Bulletin*, Number 223. *Obstet Gynecol*, 135(6):e261-e274.
- Andersen SL, et al. 2013. Birth Defects after early pregnancy use of antithyroid drugs: A Danish nationwide study. *J Clin Endocrinol Metab*, 98(11):4374-4381.
- Andersen SL, et al. 2017. Birth Defects after early pregnancy use of antithyroid drugs: A Swedish nationwide study. *Euro J Endocrinol*, 177(4):369-378.
- Andersen SL, Andersen S. 2020. Antithyroid drugs and birth defects. *Thyroid Res*, 13:11.
- Arata N, et al. 2012. Pregnancy outcomes of exposure to methimazole (POEM) study: an interim report. *Japanese journal of clinical medicine*, 70(11):1976-1982.
- Awosika AO, et al. 2023. Methimazole. *StatPearls* [Internet], Treasure Island (FL), available from: <https://www.ncbi.nlm.nih.gov/books/NBK545223/>
- Azizi F. 2003. Thyroid function in breast-fed infants is not affected by methimazole-induced maternal hypothyroidism: results of a retrospective study. *J Endocrinol Invest*, 26:301-304.
- Baid SK, Merke DP. 2007. Aplasia cutis congenita following in utero methimazole exposure. *J Pediatr Endocrinol Metab*, 20:585-586.
- Barbero P, et al. 2008. Choanal atresia associated with maternal hyperthyroidism treated with methimazole: a case-control study. *Am J Med Genet*, 146A(18):2390-2395.
- Cassina M, et al. 2012. Pharmacologic treatment of hyperthyroidism during pregnancy. *Birth Defects Res A Clin Mol Teratol*, 94(8):612-619.
- Chan GW, Mandel SJ. 2007. Therapy insight: management of Graves' disease during pregnancy. *Nat Clin Pract Endocrinol Metab*; 3(6):470-8.
- Chen CH, et al. 2011. Risk of adverse perinatal outcomes with antithyroid treatment during pregnancy: a nationwide population-based study. *BJOG*, 118:1365-1373.
- Clementi M, et al. 1999. Methimazole embryopathy: delineation of the phenotype. *Am J Med Genet*, 83:43-46.
- Committee on Drugs, American Academy of Pediatrics. 2001. The transfer of drugs and other chemicals into human breast milk. *Pediatrics*, 108:776-789.
- Cooper DS. 1987. Antithyroid drugs: to breast-feed or not to breast-feed. *Am J Obstet Gynecol*, 157:234-235.
- Diav-Citrin O, Ornoy A. 2002. Teratogen update: antithyroid drugs-methimazole, carbimazole, and propylthiouracil. *Teratology*, 65:38-44.
- Di Gianantonio E, et al. 2001. Adverse effects of prenatal methimazole exposure. *Teratology*, 64(5):262-266.
- Dumitrescu MC, et al. 2002. Choanal stenosis, hypothelia, deafness, recurrent dacryocystitis, neck fistulas, short stature, and microcephaly: report of a case. *Am J Med Genet*, 113:295-297.
- Dumitrascu MC, et al. 2021. Hyperthyroidism management during pregnancy and lactation (Review). *Exp Ther Med*, 22(3):960.
- Eisenstein Z, et al. 1992. Intellectual capacity of subjects exposed to methimazole or propylthiouracil in utero. *Eur J Pediatr*, 151:558-559.
- Ferraris S, et al. 2003. Malformations following methimazole exposure in utero: an open issue. *Birth Defects Res*

(Part A), 67:989-992.

- Francis T, et al. 2020. Safety of antithyroid drugs in pregnancy: update and therapy implications. *Expert Opin Drug Saf*, 19(5):565-576.
- Gianetti E, et al. 2015. Pregnancy outcome in women treated with methimazole or propylthiouracil during pregnancy. *J Endocrinol Invest*, 38(9):977-985.
- Greenberg F. 1987. Brief clinical report: Choanal atresia and athelia: Methimazole teratogenicity or a new syndrome? *Am J Med Genet*, 28:931-934.
- Gripp KW, et al. 2011. Grade 1 microtia, wide anterior fontanel and novel type trachea-esophageal fistula in methimazole embryopathy. *Am J Med Genet A*, 155A(3):526-533.
- Howley MM, et al. 2017. Thyroid medication use and birth defects in the National Birth Defects Prevention Study. *Birth Defects Res*, 109(18):1471-1481.
- Hudzik B, Zubelewicz-Szkodzinska B. 2016. Antithyroid drugs during breastfeeding. *Clin Endocrinol (Oxf)*, 85(6):827-830.
- Johnsson E, et al. 1997. Severe malformations in infant born to hyperthyroid woman on methimazole. *Lancet*, 350:1520.
- Karlsson FA, et al. 2002. Severe embryopathy and exposure to methimazole in early pregnancy. *J Clin Endocrinol Metab*, 87(2):947-949.
- Korelitz JJ, et al. 2013. Prevalence of thyrotoxicosis, antithyroid medication use, and complications among pregnant women in the United States. *Thyroid*, 23:758-765.
- Martin-Denavit T, et al. 2000. Ectodermal abnormalities associated with methimazole intrauterine exposure [letter]. *Am J Med Genet*, 94:338-340.
- Methimazole tablets, USP Prescribing Information. Par Pharmaceutical Companies, Inc. Spring Valley, NY 10977. Accessed May 2024. https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/040350s016lbl.pdf
- Mitsuda N, et al. 1992. Risk factors for developmental disorders in infants born to women with Graves disease. *Obstet Gynecol*; 80(3 Pt 1):359-64.
- Momotani M, et al. 1984. Maternal hyperthyroidism and congenital malformation in the offspring. *Clin Endocrinol (Oxford)*, 20:695-700.
- Purnamasari D, et al. 2019. Gastroschisis Following Treatment with High-Dose Methimazole in Pregnancy: A Case Report. *Drug Saf Case Rep*, 6(1):5.
- Radetti G, et al. 2002. Foetal and neonatal thyroid disorders. *Minerva Pediatr*; 54(5):383-400.
- Rasmussen SA, et al. 2007. Maternal thyroid disease as a risk factor for craniosynostosis. *Obstetrics and gynecology*, 110(2 Pt 1):369-377.
- Romeo AF, Obican SG. 2020. Teratogen Update: Antithyroid Medications. *Birth Defects Res*, 112(15):1150-1170.
- Sargent KA, et al. 1994. Apparent scalp-ear-nipple (Findlay) syndrome in a neonate exposed to methimazole in-utero. *Am J Hum Genet*, 55:A312.
- Sato Y, et al. 2014. A case of fetal hyperthyroidism treated with maternal administration of methimazole. *J Perinatol*, 34(12):945-347.
- Seo GH, et al. 2018. Antithyroid drugs and congenital malformations. A nationwide Korean cohort study. *Ann Intern Med*, 168(6):405-413.
- Seoud M, et al. 2003. Gastrointestinal malformations in two infants born to women with hyperthyroidism untreated in the first trimester. *Am J Perinatol*, 20:59-62.
- Shepard TH, et al. 2002. Update on new developments in the study of human teratogens. *Teratology*, 65(4):153-161.
- Stagnaro-Green A, et al. 2011. Guidelines of the American Thyroid Association for the diagnosis and management of thyroid disease during pregnancy and postpartum. *Thyroid*, 21:1081-1125.
- Tegler L, Lindstrom B. 1980. Antithyroid drugs in milk. *Lancet*, 2:591.
- The WHO Working Group, Bennet PN (ed). 1988. *Drugs and Human Lactation*. Elsevier, Amsterdam, New York, Oxford, pp. 196-197.

- Tonacchera M, et al. 2020. Treatment of Graves' hyperthyroidism with thionamides: a position paper on indications and safety in pregnancy. J Endocrinol Invest, 43(2):257-265.
- Wilson LC, et al. 1998. Choanal atresia and hypothelia following methimazole exposure in utero: a second report. Am J Med Genet, 75:220-222.

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Selected References:

- Camera G and Pregliasco P. 1992. Ear malformation in baby born to mother using isotretinoin cream. Lancet, 339:687.
- De Wals P, et al. 1991. Association between holoprosencephaly and exposure to topical retinoids: results of the EUROCAT survey. Paediatr Perinat Epidemiol, 5:445-447.
- Jick S, et al. 1993. First trimester topical tretinoin and congenital disorders. Lancet, 341:1181-1182.
- Kaplan YC, et al. 2015. Pregnancy outcomes following first-trimester exposure to topical retinoids: A systematic review and meta-analysis. Br J Dermatol, 173:1132-1141.
- Loureiro KD, et al. 2005. Minor malformations characteristic of the retinoic acid embryopathy and other birth outcomes in children of women exposed to topical tretinoin during early pregnancy. American Journal of Medical Genetics, 136A:117-121.
- Lipson AH, et al. 1993. Multiple congenital defects associated with maternal use of topical tretinoin. Lancet, 341:1352-1353.
- MacDonald SC, et al. 2019. Identifying pregnancies in insurance claims data: Methods and application to retinoid teratogenic surveillance. Pharmacoepidemiol Drug Saf 28(9):1211-1221.
- Panchaud A, et al. 2012. Pregnancy outcome following exposure to topical retinoids: a multicenter prospective study. J Clin Pharmacol, 52:1844-1851.

- Ross SA, et al. 2000. Retinoids in embryonal development. *Physiol Rev*, 80(3):1021-1054.
- Selcen D, et al. 2000. Otocerebral anomalies associated with topical tretinoin use. *Brain Dev* 22:218-220.
- Shapiro L, et al. 1997. Safety of first trimester exposure to topical tretinoin: prospective cohort study. *Lancet*, 350:1143-1144.
- Veraldi S, et al. 2016. Are topical retinoids teratogenic? *G Ital Dermatol Venereol*. 151(6):700-705.
- Williams AL et al. 2020. Teratogen update: Topical use and third-generation retinoids. *Birth Defects Res*, 112(15):1105-1114.

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