

Diphenhydramine

Selected References:

- Abernathy A, et al. 2017. Transient fetal tachycardia after intravenous diphenhydramine administration. *Obstet* 130(2):374-376.
- Aldridge T, et al. 2014. First-trimester antihistamine exposure and risk of spontaneous abortion or preterm birth. *Pharmacoepidemiol Drug Saf.* Oct 23 (10):1043-50.
- Anderka M, et al, and the National Birth Defects Prevention Study. 2012. Medications used to treat nausea and vomiting of pregnancy and the risk of selected birth defects. *Birth Defects Res (Part A)* 94:22-30.
- Aselton P, et al. 1985. First-trimester drug use and congenital disorders. *Obstet Gynecol* 65(4):451-455.
- Brost BC, et al. 1996. Diphenhydramine overdose during pregnancy: Lessons from the past. *Am J Obstet Gynecol* 175:1376-7.
- Black RA, et al. 2003. Over-the-Counter Medications in Pregnancy. *Am Fam* 67(12):2517-2524.
- Brzezińska-Wcisło L, et al. 2017. Pregnancy: a therapeutic dilemma. *Adv Dermatol Allergol:XXXIV* (5): 433-438.
- Chaudhry SK & Susser LC. 2018. Considerations in treating insomnia during pregnancy: a literature review. *Psychosomatics*, 59(4), 341-348.
- Cohen F, et al. 2021. A randomized study of IV prochlorperazine plus diphenhydramine versus IV hydromorphone for migraine-associated symptoms: A post hoc analysis. *Headache*. 61(8):1227-1233.
- Friedman BW, et al. 2016. Diphenhydramine as Adjuvant Therapy for Acute Migraine: An Emergency Department-Based Randomized Clinical Trial. *Ann Emerg Med*. 67(1):32-39.
- Gilboa SM, et al. 2009. National Birth Defects Prevention Study: Use of antihistamine medications during early pregnancy and isolated major malformations. *Birth Defects Res A Clin Mol Teratol* 85(2):137-150.
- Hansen C, et al. 2020. Use of antihistamine medications during early pregnancy and selected birth defects: The National Birth Defects Prevention Study, 1997–2011. *Birth Defects Research*, 112(16), 1234-1252.
- Hara GS, et al. 1980. Dramamine in labor: potential boon or a possible bomb? *J Kans Med Soc* 81(3):134-136, 155.
- Ito S, et al. 1993. Prospective follow-up of adverse reactions in breast-fed infants exposed to maternal medication. *Am J Obstet Gynecol* 168:1393-9.
- Kargas GA, et al. 1985. Perinatal mortality due to interaction of diphenhydramine and temazepam. *N Eng J Med* 313:1417-8.
- Li Q, et al. 2013. Assessment of antihistamine use in early pregnancy and birth defects. *J Allergy Clin Immunol Pract.* 1(6):666-e1.
- McLafferty LP, et al. 2018. Pharmacologic treatment of sleep disorders in Sleep medicine clinics, 13(2), 243-250.
- Miller MA, et al. 2020. Sleep pharmacotherapy for common sleep disorders in pregnancy and lactation. *Chest*, 157(1), 184-197.
- Moraes AP, et al. 2004. Maternal exposure to diphenhydramine during the fetal period in rats: effects on physical and neurobehavioral development and on neurochemical parameters. *Neurotoxicol Teratol* 26(5):681-692.
- Moretti ME, et al. 1995. Adverse events in breastfed infants exposed to antihistamines in maternal milk. *Reprod Toxicol* 9: 588.
- O'Brien TE. 1974. Excretion of drugs in human milk. *Am J Hosp Pharm* 31:844-54.
- Parken DE. 1974. Probably Benadryl withdrawal manifestations in a newborn infant. *J Pediatr* 85:580.
- Saldanha IJ, et al. 2021. Management of primary headaches during pregnancy, postpartum, and breastfeeding: A systematic review. *Headache*, 61(1):11-43.
- Saxen I. 1974. Cleft palate and maternal diphenhydramine intake. *Lancet* 1(7854):407-408.

- Shenai N, et al. 2018. Fetal outcomes in intentional over-the-counter medication overdoses in Psychosomatics 4:400-404.
- So M, et al. 2010. Safety of antihistamines during pregnancy and lactation. Can Fam Physician 56(5):427-429.
- Spencer JP, et al. 2001. Medications in the Breast-feeding Mother. Am Fam Physician 64(1): 119-127.
- Wolfson AR, et al. 2022. Diphenhydramine: Time to Move on? J Allergy Clin Immunol Pract. 10(12):3124-313.

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Diphenhydramine

Selected References:

- Andersen JT, et al. 2014. Exposure to selective serotonin reuptake inhibitors in early pregnancy and the risk of miscarriage. Obstet Gynecol 124: 655-661.
- Anderson KN, et al. 2020. Maternal use of specific antidepressant medications during early pregnancy and the risk of selected birth defects. JAMA Psychiatry. 77(12):1246-1255
- Bérard A, et al. 2017. SSRI and SNRI use during pregnancy and the risk of persistent pulmonary hypertension of the newborn. Br J Clin Pharmacol. 83(5):1126-1133.
- Berle JO, et al. 2004. Breastfeeding during maternal antidepressant treatment with serotonin reuptake inhibitors: infant exposure, clinical symptoms, and cytochrome P450 genotypes. J Clin Psychiatry. 65:1228-1234.
- Bonari L, et al. 2004. Perinatal risks of untreated depression during pregnancy. Can J Psychiatry 49(11):726-
- Chambers CD, et al. 2006. Selective serotonin-reuptake inhibitors and risk of persistent pulmonary hypertension of the newborn. N Engl J Med 354:579-587.
- Colvin L, et al. Dispensing patterns and pregnancy outcomes for women dispensed selective serotonin reuptake inhibitors in pregnancy. Birth Defects Research Part A: Clinical and Molecular Teratology 91:142-152
- Cornet MC, et al. Maternal treatment with selective serotonin reuptake inhibitors during pregnancy and delayed neonatal adaptation: a population-based cohort study. Arch Dis Child Fetal Neonatal Ed 18;109(3):294-300.

- Den Besten-Bertholee D, et al. Sertraline, citalopram and paroxetine in lactation: passage into breastmilk and infant exposure. *Front Pharmacol* 22(15):1414677.
- Desautay P, et al. 2024. Antidepressants and fetal death: A systematic review and disproportionality analysis in the WHO safety database (VigiBase). *Psychiatry Res* 339:
- Einarson A, et al. 2009. Incidence of major malformations in infants following antidepressant exposure in pregnancy: results of a large prospective cohort study. *Can J Psychiatry* 54(4):242-246.
- Ericson A, et al. 1999. Delivery outcome after the use of antidepressants in early pregnancy. *Eur J Clin Pharmacol* 55:503-508.
- Gao SY, et al. 2018. Selective serotonin reuptake inhibitor use during early pregnancy and congenital malformations: a systematic review and meta-analysis of cohort studies of more than 9 million births. *BMC Med* 16(1):205.
- Gram MA, et al. Antidepressant exposure patterns during pregnancy and risk of adverse newborn outcomes. *Psychiatry Res* 342:116274.
- Grigoriadis S, et al. 2013. The effect of prenatal antidepressant exposure on neonatal adaptation: a systematic review and meta-analysis. *J Clin Psychiatry*.74(4):e309-20.
- Heikkinen T, et al. 2002. Citalopram in pregnancy and lactation. *Clin Pharmacol Ther* 72:184-191.
- Jimenez-Solem E, et al. 2012. Exposure to selective serotonin reuptake inhibitors and the risk of congenital malformations: a nationwide cohort study. *BMJ Open*:2e001148 doi:10.1136/bmjopen-2012-001148.
- Jordan AE, et al. 2008. Serotonin reuptake inhibitor use in pregnancy and the neonatal behavioral syndrome. *J Matern Fetal Neonatal Med* 21(10):745-751.
- Huybrechts KF, et al. 2014. Antidepressant use in pregnancy and the risk of cardiac defects. *N Engl J Med*. 370(25):2397-407.
- Kallen BAJ and Otterblad Olausson P. 2007. Maternal use of selective serotonin re-uptake inhibitors in early pregnancy and infant congenital malformations. *Birth Defects Res A Clin Mol Teratol* 79(4):301-308.
- Kallen B and Otterblad Olausson P. 2008. Maternal use of selective serotonin re-uptake inhibitors and persistent pulmonary hypertension of the newborn. *Pharmacoepidemiol Drug Saf* 17:801-806.
- Kieler H, et al. 2012. Selective serotonin reuptake inhibitors during pregnancy and risk of persistent pulmonary hypertension in the newborn: population based cohort study from the five Nordic BMJ; 344:d8012.
- Kieviet N, et al. 2015. Risk factors for poor neonatal adaptation after exposure to antidepressants in utero. *Acta Paediatr*. 104(4):384-91.
- Louik C, et al. 2007. First-trimester use of selective serotonin-reuptake inhibitors and the risk of birth defects. *N Engl J Med* 356:2675-2683.
- Milosavljević JZ, et al. 2022. The effects of selective serotonin reuptake inhibitors on male and female fertility: a brief literature review. *Int J Psychiatry Clin Pract*. 26(1):43-49.
- Morales DR, et al. Antidepressant use during pregnancy and risk of autism spectrum disorder and attention deficit hyperactivity disorder: systematic review of observational studies and methodological considerations. *BMC Med*. 16:1-14.
- Moses-Kolko, EL, et al. 2005. Neonatal signs after late in utero exposure to serotonin reuptake inhibitors: Literature review and implications for clinical applications. *JAMA* 293:2372-2383.
- Newport DJ, et al. 2002. The treatment of postpartum depression: Minimizing infant exposure. *J Clin Psychiatry* 63(Suppl 7): 31-44.
- Rampono J, et al. 2006. Transfer of escitalopram and its metabolite demethylescitalopram into breastmilk. *Br J Clin Pharmacol* 3:316-22.
- Reefhuis J, et al. 2015. Specific SSRIs and birth defects: bayesian analysis to interpret new data in the context of previous Bmj. 351:h3190.
- Reis M and Kallen B. 2010. Delivery outcome after maternal use of antidepressant drugs in pregnancy: an update using Swedish data. *Psychol Med* 40(10):1723-1733.
- Sivojelezova A, et al. 2005. Citalopram use in pregnancy: prospective comparative evaluation of pregnancy and fetal outcome. *Am J Obstet Gynecol* 193:2004-9.

- Sjaarda LA, et al. Urinary selective serotonin reuptake inhibitors across critical windows of pregnancy establishment: A prospective cohort study of fecundability and pregnancy loss. *Fertil Steril* 114:1278-1287.
- Tabacova SA, et al. 2004. Adverse developmental events reported to FDS in association with maternal citalopram treatment in Birth Defects Res 70:361.
- Wang S, et al. 2015. Selective serotonin reuptake inhibitors (SSRIs) and the risk of congenital heart defects: A meta-analysis of prospective cohort studies. *Journal of the American Heart Association*. 4(5).
- Weissman AM, et al. 2004. Pooled analysis of antidepressant levels in lactating mothers, breast milk, and nursing infants. *Am J Psychiatry*. 161:1066-1078.

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Diphenhydramine

Selected References:

- Almas S, et al. 2016. Management of multiple sclerosis in the breastfeeding mother. *Mult Scler Int*:6527458.
- Amato MP and Portaccio E. 2015. Fertility, Pregnancy and Childbirth in Patients with Multiple Sclerosis: Impact of Disease-Modifying Drugs. *CNS Drugs* 29:207-220.
- Andersen JB, et al. 2018. Pregnancy outcomes in men and women treated with teriflunomide. A population-based nationwide Danish registry study. *Frontiers in Immunology* 9(2706):1-7.
- Aubagio® Prescribing Information. 12/2022. Available online at <http://products.sanofi.us/aubagio/aubagio.pdf>, accessed 12/2022.
- Barataud-Reilhac A, et al. 2020. Teriflunomide-exposed pregnancies in French cohort of patients with multiple sclerosis. *Neurol Clin Pract* 10(4): 287-297.
- Cree BA. 2013. Update on reproductive safety of current and emerging disease-modifying therapies for multiple sclerosis. *Mult Scler*.19:835-43.
- Chambers CD, et al. 2010. Birth outcomes in pregnant women taking leflunomide. *Arthritis Rheu*.

62(5):1494-503.

- Chambers C, et al. 2007. Are new agents used to treat rheumatoid arthritis safe to take during pregnancy? Organization of Teratology Information Specialists (OTIS) study. *Motherisk Update*. 53(3):409-412.
- Cassina M, et al. 2012. Pregnancy outcome in women exposed to Leflunomide before or during pregnancy. *Arth & Rheum* 64(7):2085-2094.
- D'Aleo G, et al. 2020. Twin pregnancy outcome following teriflunomide treatment in a relapsing-remitting multiple sclerosis patient: A case report. *Medicine (Baltimore)* 99(28):e21212.
- Davenport L, et al. 2014. Teriflunomide: non-clinical evaluation demonstrates no effect on sperm DNA or male fertility [abstract]. *Neurology* 82(10 Supp):P2.233.
- De Santis M, et al. 2005. Paternal and maternal exposure to leflunomide: pregnancy and neonatal outcome. *Ann Rheum Dis* 64:1096-1097.
- Dobson R, et al. 2019. UK consensus on pregnancy in multiple sclerosis: 'Association of British Neurologists' guidelines. *Pract Neurol*. 19:106-14
- Gold R and Wolinsky JS. 2011. Pathophysiology of multiple sclerosis and the place of teriflunomide. *Acta Neurol Scand* 124(2):75-84.
- Henson LJ, et al. 2014. Updated pregnancy outcomes in patients and partners of patients in the teriflunomide clinical trial program [abstract]. *Neurology* 82(10 Supp): P4.161.
- Kieseier B, et al. 2012. Pregnancy outcomes from the teriflunomide clinical development programme: retrospective analysis of the teriflunomide clinical trial database (Poster 737). *Mult Scler*;18(Suppl 4):328.
- Losee JE and Mason AC. 2005. Deformational plagiocephaly: diagnosis, prevention, and treatment. *Clin Plastic Surg* 31;53-64
- Lu E, et al. 2013. Safety of disease-modifying drugs for multiple sclerosis in pregnancy: current challenges and future considerations for effective pharmacovigilance. *Expert Reviews* 13(3):251-61.
- O'Connor P, et al. 2011: Randomized trial of oral teriflunomide for relapsing multiple sclerosis. *N Engl J Med* 365(14):1293-1303.
- Varytė G, et al. 2021. Pregnancy and multiple sclerosis: an update. *Curr Opin Obstet Gynecol* 33(5):378-383.
- Vukusic S, et al. 2020. Pregnancy outcomes in patients with multiple sclerosis treated with teriflunomide: Clinical study data and 5 years of post-marketing experience. *Mult Scler* 26(7):829-836.
- Weber-Schoendorfer C, et al. 2017. Leflunomide – A human teratogen? A still not answered question. An evaluation of the German Embryotox pharmacovigilance database. *Reprod Toxicol* 71:101-107.

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Diphenhydramine

Selected References:

- Bach V, et al. 1989. A randomized comparison between midazolam and thiopental for elective cesarean section anesthesia. III. Placental transfer and elimination in neonates. *Anesth Analg*. 68:238-42.
- Frolich MA, et al. 2006. A single dose of fentanyl and midazolam prior to Cesarean section have no adverse neonatal effects. *Can J Anaesth*. 53(1):79-85.
- Iyilikci L, et al. 2007. Sedation for endoscopic retrograde cholangiopancreatography (ERCP) in a pregnant patient. *J Anesth*. 21(1):69-71.
- Kanto J, et al. 1984. Pharmacokinetics and sedative effect of midazolam in connection with cesarean section performed under epidural analgesia. *Acta Anaesthesiol Scand* 28:116-8.
- Kelly LE, et al. 2012. Neonatal Benzodiazepines Exposure during Breastfeeding. *J Pediatr*. 161(3):448-451.
- Koitabashi T, et al. 1997. Intravenous midazolam passage into breast milk. *J Anesth*. 11:242-3.
- Nitsun M, et al. 2006. Pharmacokinetics of midazolam, propofol, and fentanyl transfer to human breast milk. *Clin Pharmacol* 79:549-57.
- Olutoye OA, et al. 2018. Food and Drug Administration warning on anesthesia and brain development: implications for obstetric and fetal surgery. *Am J Obstet* 218(1):98-102.
- Senel AC, et al. 2014. Premedication with midazolam prior to caesarean section has no neonatal adverse effects. *Braz J Anesthesiol*. 64(1):16-21.
- Shergill AK, et al. 2012. Guidelines for endoscopy in pregnant and lactating women. *Gastrointest Endosc*. 76(1):18-24.
- Swanson RJ, Leavitt MG. 1992. Fertilization and mouse embryo development in the presence of midazolam. *Anesth Analg* 75: 549-54, 1992.
- Uguz A New Safety Scoring System for the Use of Psychotropic Drugs During Lactation. *Am J Ther*. 2021 Jan-Feb 01;28(1):e118-e126. doi: 10.1097/MJT.0000000000000909. PMID: 30601177.
- Wilson CM, et al. 1987. A comparison of the early pharmacokinetics of midazolam in pregnant and nonpregnant women. *Anaesthesia*. 42:1057-62.
- Xu J, et al 2019. Early Developmental Exposure to Repetitive Long Duration of Midazolam Sedation Causes Behavioral and Synaptic Alterations in a Rodent Model of Neurodevelopment. *J Neurosurg Anesthesiol*. 31(1):151-
- Young C, et al. 2005. Potential of ketamine and midazolam, individually or in combination, to induce apoptotic neurodegeneration in the infant mouse brain. *Br J Pharmacol*. 146(2):189-97.

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Selected References:

- Holt RI, Peveler RC. 2011. Antipsychotics and hyperprolactinemia: mechanisms, consequences and management. Clin Endocrinol (Oxf). 74(2):141-7.
- Einarson A, Boskovic R. 2009. Use and safety of antipsychotic drugs during pregnancy. J Psychiatr Pract. 15(3):183-92.
- Loxitane® Product Label. Revised 2017. Available at URL: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/017525s051,017658s038,018039s024lbl.pdf
- Maguire GA. 2002. Prolactin elevation with antipsychotic medications: mechanisms of action and clinical consequences. J Clin Psychiatry. 63 Suppl 4:56-62.
- Parikh T, et al. 2014. Antipsychotic drugs and safety concerns for breast-feeding infants. South Med J. 107(11):686-8.
- Torre, DL, and Falorni, A. 2017. Pharmacological causes of hyperprolactinemia. Therapeutics and clinical risk management. 3(5): 929-51.

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