

Ondansetron (Zofran®)

Selected References:

- Andrade C. 2020. Major Congenital Malformation Risk After First Trimester Gestational Exposure to Oral or Intravenous Ondansetron. *J Clin Psychiatry*;81(3):20f13472
- Anderka M, et al. 2012. Medications used to treat nausea and vomiting of pregnancy and the risk of selected birth defects. *Birth Defects Res A Clin Mol Teratol*; 94(1):22-30.
- Briggs GG, Freeman RK. 2014. *Drugs in Pregnancy and Lactation*. 10th edition. Philadelphia, PA: Wolters Kluwer (online version).
- Cao X, et al. 2022. Risk of abnormal pregnancy outcomes after using ondansetron during pregnancy: A systematic review and meta-analysis. *Front Pharmacol*, 13(951072).
- Cohen R, et al. 2014. Intestinal obstruction in pregnancy by ondansetron. *Reprod Toxicol*. 2014 Oct 24;50C:152-153.
- Cho Y, et al. 2025. Antiemetic use during pregnancy and child neurodevelopment: population-based birth cohort study. *BMC medicine*, 23(1), 667.
- Colvin L, et al. 2013. Off-label use of ondansetron in pregnancy in Western Australia. *Biomed Res Int*. 2013:909860.
- Danielsson B, Wikner BN, Kallen B. 2014. Use of ondansetron during pregnancy and congenital malformations in the infant. *Reprod Toxicol* 50:134-7.
- Diav-Citrin O, et al. 2017. Pregnancy outcome following in utero exposure to ondansetron: A prospective comparative, observational cohort study. *Reprod Toxicol*; 72:203.
- Dormuth CR, et al; Canadian Network for Observational Drug Effect Studies (CNODES) Investigators. 2021. Comparison of Pregnancy Outcomes of Patients Treated with Ondansetron vs Alternative Antiemetic Medications in a Multinational, Population-Based Cohort. *JAMA Netw Open*; 4(4):e215329.
- Einarson AK, et al. 2004. The safety of ondansetron for nausea and vomiting of pregnancy: a prospective comparative study. *BJOG*;111:940-3.
- Elkomy MH, et al. 2015. Ondansetron pharmacokinetics in pregnant women and neonates: towards a new treatment for neonatal abstinence syndrome. *Clin Pharmacol Ther*. 97:167-76.
- Fejzo MS, et al. 2016. Ondansetron in pregnancy and risk of adverse fetal outcomes in the United States. *Reprod Toxicol* 62: 87-91.
- Food and Drug Administration. 2012. FDA Drug Safety Communication: New information regarding QT prolongation with ondansetron (Zofran). <https://downloads.regulations.gov/FDA-2016-N-2462-0013/content.pdf>. Accessed 2018, 2022, and 2026.
- Huybrechts KF, et al. 2018. Association of Maternal First-Trimester Ondansetron Use With Cardiac Malformations and Oral Clefts in Offspring. *JAMA*, 320(23), 2429-2437.
- Jelting Y, et al. 2017. Preventing nausea and vomiting in women undergoing regional anesthesia for cesarean section: Challenges and solutions. *Local Reg Anesth*, 10:83-90.
- Kaplan YC, et al. 2019. Use of ondansetron during pregnancy and the risk of major congenital malformations: A systemic review and meta-analysis. *Reprod Toxicol*; 86 Jun:1-13.
- Larrimer MB, et al. 2014. Antiemetic medications in pregnancy: a prospective investigation of obstetric and neurobehavioral outcomes. *Am J Obstet Gynecol* 210 (3): 270. e1-7
- Laspro M, et al. 2025. Association of Commonly Prescribed Antepartum Medications and Incidence of Orofacial Clefting. *The Cleft palate-craniofacial journal : official publication of the American Cleft Palate-Craniofacial Association*, 62(7), 1164-1174
- Lavecchia M, et al. 2018. Ondansetron in Pregnancy and the Risk of Congenital Malformations: A Systematic Review. *J Obstet Gynaecol Can*. 40(7):910-918.
- Lemon LS, et al. 2020. Ondansetron use in the first trimester of pregnancy and the risk of neonatal ventricular

septal defect. *Int J Epidemiol*;49(2):648-656.

- Masarwe S, et al. 2023. Ondansetron use during pregnancy: Birth defects and obstetric outcomes. *Clin Nurs Res*, 32(4):705-711.
- Pasternak B. 2013. Ondansetron in pregnancy and risk of adverse fetal outcomes. *N Engl J Med* 368:814-823.
- Picot C, et al. 2020. Risk of malformation after ondansetron in pregnancy: An updated systemic review and meta-analysis. *Birth Defects Res*;112(13):996-1013.
- Reis ACC, et al. 2023. Safety evaluation of ondansetron after gestational exposure on male reproductive parameters in rats. *Regul Toxicol Pharmacol*, 137:105302.
- Sakran R, et al. 2021. Pregnancy outcome following in-utero exposure to ondansetron: A prospective comparative observational study. *Reprod Toxicol*; 99:9-14.
- Schrager NL, et al. 2023. The association of nausea and vomiting of pregnancy, its treatments, and select birth defects: Findings from the National Birth Defect Prevention Study. *Birth Defects Res*, 115(3):275-289.
- Sillis L, et al. 2026. Medications for Nausea and Vomiting of Pregnancy and the Risks for Adverse Birth Outcomes. *Pharmacoepidemiology and drug safety*, 35(4), e70367.
- Suarez EA, et al. 2021. Ondansetron use in early pregnancy and the risk of late pregnancy outcomes. *Pharmacoepidemiol Drug Saf*; 30(2):114-125.
- Suarez EA, et al. 2021. Ondansetron use in early pregnancy and the risk of miscarriage. *Pharmacoepidemiol Drug Saf*; 30(2):103-113.
- Tolchinsky I, et al. 2026 Another prospective study on the safety of ondansetron for nausea and vomiting of pregnancy: addressing ongoing concerns. *Front. Pharmacol.* 17:1783632.
- Yang J, 2026. Ondansetron Use for Women With Hyperemesis Gravidarum and Risks of Spontaneous Abortion and Stillbirth: A Retrospective Cohort Study. *Pharmacoepidemiology and drug safety*, 35(2), e70335.
- Zhao W, et al. 2020. Retrospective comparison of the safety and effectiveness of dexmedetomidine versus standard of care before and during cesarean delivery in a maternity unit in Zhengzhou, China. *Med Sci Monit*, 26:e925709.

¿Preguntas? Llame al 866.626.6847 | Texto 855.999.3525 | Correo electrónico o chat en [MotherToBaby.org](https://www.MotherToBaby.org) .

Descargo de responsabilidad: las hojas informativas de MotherToBaby están destinadas a fines de información general y no deben reemplazar los consejos de su proveedor de atención médica. MotherToBaby es un servicio de la Organización sin fines de lucro de Especialistas en Información de Teratología (OTIS). Copyright de OTIS, 1 de mayo de 2026.

Ondansetron (Zofran®)

Selected References:

- Andersen JB, et al. 2023. Pregnancy outcomes after early fetal exposure to injectable first-line treatments, dimethyl fumarate, or natalizumab in Danish women with multiple sclerosis. *European journal of neurology*; 30(1), 162-171.
- Bast N, et al. 2024. Impact of disease-modifying therapies on pregnancy outcomes in multiple sclerosis: a prospective cohort study from the German multiple sclerosis and pregnancy registry. *Lancet Reg Health Eur*; 48: 101137.
- Ciplea AI, et al. 2020. Exposure to natalizumab during pregnancy and lactation is safe -Commentary. *Multiple sclerosis (Houndmills, Basingstoke, England)*; 26(8), 892-893.
- D'Amico E, et al. 2021. Male fertility in relapsing-remitting multiple sclerosis patients treated with natalizumab and ocrelizumab: A prospective case-control study. *Multiple sclerosis (Houndmills, Basingstoke, England)*; 27(14), 2284-2287.
- Demortiere S, et al. 2021. Maintenance of natalizumab during the first trimester of pregnancy in active multiple sclerosis. *Mult Scler*; 27(5):712-718.
- Ebrahimi N, et al. 2015. Pregnancy and fetal outcomes following natalizumab exposure in pregnancy. A prospective, controlled observational study. *Mult Scler*; 21(2):198-205.
- Friend S, et al. 2016. Evaluation of pregnancy outcomes from the Tysabri (natalizumab) pregnancy exposure registry: a global, observational, follow-up study. *BMC Neurol*; 16(1):150
- Gklinos P, et al. 2023. Monoclonal Antibodies in Pregnancy and Breastfeeding in Patients with Multiple Sclerosis: A Review and an Updated Clinical Guide. *Pharmaceuticals (Basel, Switzerland)*; 16(5),770.
- Godano E, et al. 2021. Erythropoietin therapy in a case of neonatal anemia after exposure to natalizumab throughout pregnancy. *Ital J Pediatr*; 47, 69.
- Guilloton L, et al. 2017. Neonatal pancytopenia in a child, born after maternal exposure to natalizumab throughout pregnancy. *J Gynecol Obstet Hum Reprod*; 46(3): 301-302.
- Haghighi A, et al. 2014. Natalizumab use during the third trimester of pregnancy. *JAMA Neurol*; 71(7): 891-895.
- Krysko KM, et al. 2023. Family planning considerations in people with multiple sclerosis. *Lancet Neurol*; 2023;22:350-66.
- Landi D, et al. 2022. Exposure to natalizumab throughout pregnancy: effectiveness and safety in an Italian cohort of women with multiple sclerosis. *J Neurol Neurosurg Psychiatry jnnp-2022-329657*.
- Mahadevan U, et al. 2019. Inflammatory bowel disease in pregnancy clinical care pathway: a report from the American Gastroenterological Association IBD Parenthood Project Working Group. *Gastroenterology*; 156(5):1508-1524.
- Mahadevan U, et al. 2023. Global consensus statement on the management of pregnancy in inflammatory bowel disease. *Clin Gastroenterol Hepatol* 2025;23(Suppl 11):S1-S60.
- Matro R, et al. 2018. Exposure concentrations of infants breastfed by women receiving biologic therapies for inflammatory bowel diseases and effects of breastfeeding on infections and development. *Gastroenterology*; 155:696-704.
- Massarotti C, et al. 2021. Effect of Multiple Sclerosis and Its Treatments on Male Fertility: Cues for Future Research. *Journal of clinical medicine*; 10(22), 5401
- O'Leary S, et al. 2023. Practical Clinical Guidelines for Natalizumab Treatment in Patients With Relapsing Multiple Sclerosis. *Journal of infusion nursing: the official publication of the Infusion Nurses Society*; 46(6), 347-359.
- Oreja-Guevara C, et al. 2023. Family Planning in Fertile-Age Patients With Multiple Sclerosis (MS) (ConPlanEM Study): Delphi Consensus Statements. *Cureus*; 15(8), e44056
- Peng A, et al. 2018. Natalizumab exposure during pregnancy in multiple sclerosis: a systematic review. *J Neurol*

Sci; 396:202-205.

- Portaccio E, et al. 2018. Pregnancy decision-making in women with multiple sclerosis treated with natalizumab: I: Fetal risks. *Neurology*; 90(10), e823-e831.
- Portaccio E, et al. 2022. Natalizumab treatment and pregnancy in multiple sclerosis: A reappraisal of maternal and infant outcomes after 6 years. *Mult Scler*; 28(13):2137-2141.
- Simone IL, et al. 2021. Influence of Pregnancy in Multiple Sclerosis and Impact of Disease-Modifying Therapies. *Frontiers in neurology*; 12, 697974.
- Ramesh V, et al. 2022. Adverse Obstetric Outcomes in Pregnant Women Using Natalizumab for the Treatment of Multiple Sclerosis: A Systematic Review. *Cureus*; 14(10), e29952
- Shipley J, et al. 2025. Consensus recommendations on multiple sclerosis management in Australia and New Zealand: part 2. *Med J Aust*; 222:365-71.
- Siracusano M, et al. 2025. Maternal multiple sclerosis and offspring's developmental and behavioral profile: a case-control study. *Curr Neuropharmacol*; doi: 10.2174/011570159X370866250416103923. Epub ahead of print.
- Thiel S, et al. 2024. Disease activity and neonatal outcomes after exposure to natalizumab throughout pregnancy. *J Neurol Neurosurg Psychiatry*; 95(6): 561-570.
- U.S. Food and Drug Administration. 2025. Tysabri (natalizumab) injection, for intravenous use: Prescribing information. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/125104s984lbl.pdf
- Yeh WZ, et al. 2021. MSBase Study Group. Natalizumab, fingolimod and dimethyl fumarate use and pregnancy-related relapse and disability in women with multiple sclerosis. *Neurology*; 96(24):e2989-3002.

¿Preguntas? Llame al 866.626.6847 | Texto 855.999.3525 | Correo electrónico o chat en [MotherToBaby.org](https://www.MotherToBaby.org) .

Descargo de responsabilidad: las hojas informativas de MotherToBaby están destinadas a fines de información general y no deben reemplazar los consejos de su proveedor de atención médica. MotherToBaby es un servicio de la Organización sin fines de lucro de Especialistas en Información de Teratología (OTIS). Copyright de OTIS, 1 de mayo de 2026.

Ondansetron (Zofran®)

Selected References:

- Biocon Biologics Inc. 2025. Semglee Product Label. National Institute of Health DailyMed database. Available at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?>. Accessed May 2025.
- Bruttomesso D, et al. 2011. Type 1 diabetes control and pregnancy outcomes in women treated with continuous subcutaneous insulin infusion (CSII) or with insulin glargine and multiple daily injections of rapid-acting insulin analogues (glargine-MDI). *Diabetes Metab*; 37(5):426-431.
- Callesen NF, et al. 2013. Treatment with the long-acting insulin analogues detemir or glargine during pregnancy in women with type 1 diabetes: comparison of glycaemic control and pregnancy outcome. *J Matern Fetal Neonatal Med*; 26(6):588-592.
- Chico A, et al. 2016. Glycemic control and maternal and fetal outcomes in pregnant women with type 1 diabetes according to the type of basal insulin. *Eur J Obstet Gynecol Reprod Biol*; 206: 84-91.
- de Jong J, et al. 2016. Insulin analogues in pregnancy and specific congenital anomalies: a literature review. *Diabetes Metab Res Rev*; 32(4): 366-375.
- Di Cianni G, et al. 2005. Use of insulin glargine during the first weeks of pregnancy in five type 1 diabetic women. *Diabetes Care*; 28:982-983.
- Di Cianni G, et al. 2008. Perinatal outcomes associated with the use of glargine during pregnancy. *Diabet Med*; 25(8):993-996.
- Dolci M, et al. 2005. Use of glargine insulin before and during pregnancy in a woman with type 1 diabetes and Addison's Disease. *Diabetes Care*; 28:2084-2085.
- Eli Lilly and Company. 2025. Basaglar Product Label. National Institute of Health DailyMed database. Available at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?>. Accessed May 2026.
- Gallen IW, et al. 2008. Survey of glargine use in 115 pregnant women with Type 1 diabetes. *Diabet Med*; 25(2):165-169.
- Holstein A, et al. 2003. Use of insulin glargine during embryogenesis in a pregnant woman with type 1 diabetes. *Diabet Med*; 20:779-780.
- Imbergamo MP, et al. 2008. Use of glargine in pregnant women with type 1 diabetes mellitus: a case-control study. *Clin Ther*; 30(8):1476-1484.
- Lapolla A, et al. 2005. Insulin therapy in pregnancy complicated by diabetes: are insulin analogs a new tool? *Diabetes Metab Res Rev*; 21:241-52.
- Lepercq J, et al. 2010. Use of insulin glargine throughout pregnancy in 102 women with type 1 diabetes. *Diabetes Metab*; 36(3):209-212.
- Negrato CA, et al. 2010. Glargine vs. NPH insulin therapy in pregnancies complicated by diabetes: an observational cohort study. *Diabetes Res Clin Pract*; 89(1):46-51.
- Pantalone KM, et al. 2011. Glargine vs. NPH insulin therapy in pregnancies complicated by diabetes: an observational cohort study-comment on Negrato et al. *Diabetes Res Clin Pract*; 93(1):e9-10.
- Pantalone KM, et al. 2011. Insulin glargine use during pregnancy. *Endocr Pract*; 17(3):448-55.
- Pollex E, et al. 2011. Safety of insulin glargine use in pregnancy: a systematic review and meta-analysis. *Ann Pharmacother*; 45(1):9-16.
- Price N, et al. 2007. Use of insulin glargine during pregnancy: a case-control pilot study. *BJOG*; 114(4):453-457.
- Sanofi-Aventis U.S. 2023. Lantus Product Label. National Institute of Health DailyMed database. Available at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?>. Accessed May 2026.
- Sonfi-Aventus U.S. 2025. Toujeo Product Label. National Institute of Health DailyMed database. Available at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?>. Accessed May 2026.
- Torlone E, et al. 2007. Successful use of insulin glargine during entire pregnancy until delivery in six Type 1 diabetic women. *Eur J Obstet Gynecol Reprod Biol*; 132(2):238-239.
- Westerbacka J, et al. 2025. Insulin glargine 300 U/mL safety data in pregnancy. *Diabetes Obes Metab*; 27(5):2322-2325.
- Woolderink JM, et al. 2005. Use of insulin glargine during pregnancy in seven type 1 diabetic women. *Diabetes Care*; 28:2594-2595.

¿Preguntas? Llame al 866.626.6847 | Texto 855.999.3525 | Correo electrónico o chat en MotherToBaby.org.

Descargo de responsabilidad: las hojas informativas de MotherToBaby están destinadas a fines de información general y no deben reemplazar los consejos de su proveedor de atención médica. MotherToBaby es un servicio de la Organización sin fines de lucro de Especialistas en Información de Teratología (OTIS). Copyright de OTIS, 1 de mayo de 2026.

Ondansetron (Zofran®)

Selected References:

- Albze W, et al. 2023. Efficacy and safety of preoperative melatonin for women undergoing cesarean section: a systematic review and meta-analysis of randomized placebo-controlled trials. *Medicina (Kaunas)*, 59(6):1065.
- Alkhfaji H, et al. 2023. Impact of melatonin as a premedication agent in caesarean section on blood loss and postoperative pain level. *Anesthesiol Res Pract*, 2023:8102111.
- Amaral FGD and José C. 2018. A brief review about melatonin, a pineal hormone. *Archives of Endocrinology and Metabolism*, 62(4):472-479
- American Academy of Neurology. 2019. Practice guideline: Treatment for insomnia and disrupted sleep behavior in children and adolescents with autism spectrum disorder. Accessed May 11. 2026 from <https://pmc.ncbi.nlm.nih.gov/articles/PMC7238942/>
- Andersen LP, et al. 2016. The safety of melatonin in humans. *Clin Drug Investig*; 36:169-175.
- Davis, F. C. (1997). Melatonin: role in development. *Journal of Biological Rhythms*; 12(6):498-508.
- Díaz E, et al. 2000. Effect of prenatal melatonin on the gonadotropin and prolactin response to the feedback effect of testosterone in male offspring. *The Journal of Steroid Biochemistry and Molecular Biology*; 72(1):61-69.
- Díaz, E, et al. 1999. Prenatal melatonin exposure influences the maturation of gonadotropin and prolactin estradiol-benzoate feedback system. *The Journal of Steroid Biochemistry and Molecular Biology*; 70(1): 81-88.
- Ejaz F, et al. 2020. Maternal serum melatonin increases during pregnancy and falls immediately after delivery implicating the placenta as a major source of melatonin. *Frontiers in Endocrinology (Lausanne)*; 11:623038-623038.
- Garofoli F, et al. 2023. Fate of melatonin orally administered in preterm newborns: antioxidant performance and basis for neuroprotection. *J Pineal Res*; 76(1):e12932.
- Garofoli F, et al. 2021. Oral melatonin as a new tool for neuroprotection in preterm newborns: study protocol for a randomized controlled trial. *Trials*; 22(1):82.
- Gitto E, et al. 2011. Update on the use of melatonin in pediatrics. *J Pineal Res*; 50:21-8.
- Gowda SK. 2022. A comparative study to evaluate the effect of melatonin on blood loss after elective Caesarean section: a randomized double blind study. *Indian J Anaesth*; 66(Suppl 1):S17-S18.

- Grivas T, et al. 2007. Melatonin the “light of the night” in human biology and adolescent idiopathic scoliosis. *Scoliosis*; 2,6.
- Hardeland R. 2009. New approaches in the management of insomnia: weighing the advantages of prolonged-release melatonin and synthetic melatonergic agonists. *Neuropsychiatric Disease and Treatment*, 5:341–354.
- Harpsøe NG, et al. 2015. Clinical pharmacokinetics of melatonin: a systematic review. *Eur J Clin Pharmacol*, 71:901–909.
- Iavarone S, et al. 2023. Antiplatelet effect of melatonin through breastfeeding: a pediatric case report. *Children (Basel)*, 10(12):1839.
- Jayashree, et al. 2021. Effect of melatonin in reducing blood loss during and after caesarean section. *Int J Clin Obstet Gynecol*, 5(6):227-231.
- Katzer D, et al. 2016. Melatonin concentrations and antioxidative capacity of human breast milk according to gestational age and the time of day. *J Hum Lact*; 32:NP105–NP110.
- Khezri MB, et al. 2019. Effect of melatonin on blood loss after cesarean section: a prospective randomized double-blind trial. *J Obstet Gynaecol India*; 69(5):436-443.
- Luboshitzky R, et al. 2002. Melatonin administration alters semen quality in healthy men. *J Androl*; 4:572-578. Mannino G, et al. 2021. Melatonin and phytemelatonin: chemistry, biosynthesis, metabolism, distribution and bioactivity in plants and animals-an overview. *International Journal of Molecular Sciences*; 22(18):9996.
- Mejlhede MAB, et al. 2021. Oral melatonin supplementation during *in vitro* fertilization treatment: a systematic PRISMA review and meta-analysis of randomized controlled trials. *Gynecological Endocrinology*; 37(12):1079-1085.
- Moradi M, et al. 2021. Melatonin protects rats testes against bleomycin, etoposide, and cisplatin-induced toxicity via mitigating nitro-oxidative stress and apoptosis. *Biomed Pharmacother*; 138:111481.
- National Center for Complementary and Integrative Health. 2023. Attention deficit hyperactivity disorder (ADHD) and complementary health approaches: What the science says. Accessed on May 11, 2026 from <https://www.nccih.nih.gov/health/providers/digest/adhd-and-complementary-health-approaches-science>
- Okatani Y, et al. 2001. Effect of prenatal melatonin exposure on gonadotropins and prolactin secretion in male and female rat pups. *European Journal of Pharmacology*; 424(3):229-235.
- Ramiro-Cortijo D, et al. 2020. Maternal antioxidant status in early pregnancy and development of fetal complications in twin pregnancies: a pilot study. *Antioxidants*; 9(4):269
- Reiter RJ, et al. 2024. Melatonin-mediated actions and circadian functions that improve implantation, fetal health and pregnancy outcome. *Reproductive toxicology (Elmsford, N.Y.)*, 124, 108534.
- Showell MG, et al. 2020. Antioxidants for female subfertility. *Cochrane Database Syst Rev*, 8(8):CD007807.
- Sun TC, et al. 2020. Protective effects of melatonin on male fertility preservation and reproductive system. *Cryobiology*, 95:1-8
- Vine T, et al. 2022. Melatonin use during pregnancy and lactation: a scoping review of human studies. *Braz J Psychiatry*, 44(3):342-348.
- Voordouw BCG, et al. 1992. Melatonin and melatonin-progestin combinations alter pituitary-ovarian function in women and can inhibit ovulation. *J Clin Endocrinol Metab*; 74:108-17.
- Yang HL, et al. 2018. Pleiotropic roles of melatonin in endometriosis, recurrent spontaneous abortion, and polycystic ovary syndrome. *Am J Reprod Immunol*, 80(1):e12839.

¿Preguntas? Llame al 866.626.6847 | Texto 855.999.3525 | Correo electrónico o chat en MotherToBaby.org .

Descargo de responsabilidad: las hojas informativas de MotherToBaby están destinadas a fines de información general y no deben reemplazar los consejos de su proveedor de atención médica. MotherToBaby es un servicio de la Organización sin fines de lucro de Especialistas en Información de Teratología (OTIS). Copyright de OTIS, 1 de mayo de 2026.

Ondansetron (Zofran®)

Selected References:

- Anghelescu I, et al. 2004. Successful switch to aripiprazole after induction of hyperprolactinemia by ziprasidone: a case report. *J Clin Psychiatry*; 65:1286-1287.
- Biesdorf C, et al. 2019. Physiologically-based pharmacokinetics of ziprasidone in pregnant women. *Br J Clin Pharmacol*; 85(5):914-923.
- Bode'n R, et al. 2012. Antipsychotics During Pregnancy Relation to Fetal and Maternal Metabolic Effects. *Arch Gen Psychiatry*; 69(7):715-721.
- Cho H, et al. 2025. Antipsychotic use during pregnancy and outcomes in pregnant individuals and newborns. *J Affect Disord*; 373:495-504.
- Creeley CE, et al. 2019. Use of Prescribed Psychotropics during Pregnancy: A Systematic Review of Pregnancy, Neonatal, and Childhood Outcomes. *Brain Sci*; 9(9):235.
- Damkier P, Videbech P. 2018. The safety of second-generation antipsychotics during pregnancy: A clinically focused review. *CNS Drugs*. 32(4):351-366.
- Einarson A, Boskovic R. 2009. Use and safety of antipsychotic drugs during pregnancy. *J Psychiatr Pract*; 15(3):183-192.
- FDA. 2011. Drug Safety Communication: Antipsychotic drug labels updated on use during pregnancy and risk of abnormal muscle movements and withdrawal symptoms in newborns (issued 2/2011). <https://www.fda.gov/Drugs/DrugSafety/ucm243903.htm>
- FDA 2014. Drug Safety Communication: FDA reporting mental health drug ziprasidone (Geodon) associated with rare but potentially fatal skin reactions. (Issued 12/2014). <https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-reporting-mental-health-drug-ziprasidone-geodon-associated-rare>.
- Ginsberg DL. 2003. Ziprasidone-induced galactorrhea. *Prim Psychiatry*; 10:22-23.
- Ginsberg DL. 2004. Ziprasidone-induced hyperprolactinemia. *Prim Psychiatry*; 11:26-27.
- Goodnick PJ, et al. 2002. Antipsychotics: Impact on prolactin levels. *Expert Opin Pharmacother*; 3:1381-1391.
- Haddad PM, Wieck A. 2004. Antipsychotic-induced hyperprolactinaemia: mechanisms, clinical features and management. *Drugs*; 64:2291-2314.
- Heinonen E, et al. 2022. Antipsychotic Use During Pregnancy and Risk for Gestational Diabetes: A National Register-Based Cohort Study in Sweden. *CNS drugs*; 36(5):529-539.
- Humby T, Davies W. 2019. Brain gene expression in a novel mouse model of postpartum mood disorder. *Trans Neurosci*; 10:168-174.
- Huybrechts KF, et al. 2016. Antipsychotic use in pregnancy and the risk for congenital malformations. *JAMA Psychiatr*; 73(9):938-46.
- Huybrechts KF, et al. 2023. Association of In Utero Antipsychotic Medication Exposure With Risk of Congenital

Malformations in Nordic Countries and the US. *JAMA psychiatry*; 80(2):156-166.

- Jordan MP. 2003. Ziprasidone-associated galactorrhea in a female teenager. *J Am Acad Child Adolesc Psychiatry*; 42:4-5.
- Khan SJ, et al. 2016. Bipolar disorder in pregnancy and postpartum: Principles of management. *Curr Psychiatry Rep*; 18(2):13.
- Kopecek M, et al. 2005. Ziprasidone-induced galactorrhea: A case report. *Neuro Endocrinol Lett*; 26:69-70.
- Kulkarni J, et al. 2015. Antipsychotic use in pregnancy. *Expert Opin Pharmacother*; 16(9):1335-1345.
- Lusskin SI, et al. 2004. Prolactin Elevation with Ziprasidone. *American Journal of Psychiatry*; 161(10): 1925.
- Maguire GA. 2002. Prolactin elevation with antipsychotic Medications: Mechanisms of action and clinical consequences. *J Clin Psychiatry*; 63 Suppl 4:56-62.
- McCauley-Elsom K, et al. 2010. Antipsychotics in pregnancy. *Psychiat Ment Health Nurs* 17(2):97-104.
- Myers WT. 2014. A lactating adolescent on atypical antipsychotics: A case report of an emerging challenge. *J Investig Med*; 62:485.
- Park Y, et al. 2018. Continuation of atypical antipsychotic medication during early pregnancy and the risk of gestational diabetes. *Am J Psychiatry*; 175(6):564-574
- Peitl MV, et al. 2010. Ziprasidone as a possible cause of cleft palate in a newborn. *Psychiatr Danub*; 22(1):117-119.
- Ramadan M, et al. 2005. D2-blockade and possible ziprasidone-induced galactorrhea. *Int Clin Psychopharmacol*; 20:113-114.
- Raza S, Haq F. 2010. Ziprasidone-induced galactorrhea in an adolescent female: A case report. *Prim Care Companion J Clin Psych*; 12(3):PCC.09100855
- Ruzic K, et al. 2009. Pregnancy and atypical antipsychotics. *Psychiatr Danub*; 21(3):368-370.
- Saldaña SN, Delgado SV. 2007. Ziprasidone-associated galactorrhea in an adolescent female. *J Child Adolesc Psychopharmacol*; 17:259-260.
- Schlotterbeck P, et al. 2009. Low concentration of ziprasidone in human milk: a case report. *Int J Neuropsychopharmacology*; 12(3) 437-438.
- Sørensen MJ, et al. 2015. Risk of fetal death after treatment with antipsychotic medications during pregnancy. *PLoS One*; 10(7): e0132280.
- Straub L, et al. 2026. Congenital malformation risk following prenatal antipsychotic exposure: a systematic safety surveillance approach. *BMJ Ment Health*; 29(1):e302270.
- Wang E, et al. 2025. Comparative Safety of Antipsychotic Medications and Mood Stabilizers During Pregnancy: A Systematic Review and Network Meta-analysis of Congenital Malformations and Prenatal Outcomes. *CNS Drugs*; 391-22.
- Werremeyer A. 2009. Ziprasidone and citalopram use in pregnancy and lactation in a woman with psychotic depression. *Am J Psychiatry*; 166(11):1298.
- Uguz F. 2016. Second-generation antipsychotics during the lactation period: A comparative systematic review on infant safety. *J Clin Psychopharmacol*; 36:244-252.
- Uguz FJ. 2019. Antipsychotic use during pregnancy and the risk of gestational diabetes mellitus: A systematic review. *Clin Psychopharmacol*; 39(2):162-167.

¿Preguntas? Llame al 866.626.6847 | Texto 855.999.3525 | Correo electrónico o chat en [MotherToBaby.org](https://www.MotherToBaby.org) .

Descargo de responsabilidad: las hojas informativas de MotherToBaby están destinadas a fines de información general y no deben reemplazar los consejos de su proveedor de atención médica. MotherToBaby es un servicio de la Organización sin fines de lucro de Especialistas en Información de Teratología (OTIS). Copyright de OTIS, 1 de mayo de 2026.