

(®) Leflunomide (Arava

:Selected References

- Alothman R, et al. 2023. Leflunomide exposure through second trimester of pregnancy: A case report. Birth Defects Res 1;115(16):1566-1569
- Arava Prescribing Information. 2021. Available online at <http://products.sanofi.us/arava/arava.html> [https://products.sanofi.us/arava/arava.pdf [accessed Dec 2015February 2024
- Bérard A, et al. 2018. Leflunomide use during pregnancy and the risk of adverse pregnancy outcomes. Ann Rheum Dis, 77(4):500-509
- Brent RL. 2001. Teratogen update: Reproductive risks of leflunomide (Arava); A pyrimidine synthesis inhibitor: Counseling women taking leflunomide before or during pregnancy and men taking leflunomide who are contemplating fathering a child. Teratology, 63:106-112
- Briggs G, et al. 2015. Leflunomide. Drugs in Pregnancy and Lactation, A reference Guide to Fetal and Neonatal Risk, 10th edition (pp 781—784). Philadelphia, PA: Wolters Kluwer Health
- Cassina M, et al. 2012. Pregnancy outcome in women exposed to leflunomide before or during pregnancy. Arthritis Rheum, 64 (7):2085-94
- Chakravarty EF, et al. 2003. The use of disease modifying antirheumatic drugs in women with rheumatoid arthritis of childbearing age: a survey of practice patterns and pregnancy outcomes. J Rheumatol, 30:241-246
- Chambers CD, et al. 2010. Birth outcomes in pregnant women taking leflunomide. Arthritis Rheu, 62(5):1494-1503
- Chambers CD, 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
- De Santis M, et al. 2005. Paternal and maternal exposure to leflunomide: pregnancy and neonatal outcome. Ann Rheum Dis, 64:1096-1097
- Henson LJ, et al. 2020. Pregnancy outcomes in patients treated with leflunomide, the parent compound of the multiple sclerosis drug teriflunomide. Reprod Toxicol, 95:45-50
- Levy RA, et al. 2016. Critical review of the current recommendations for the treatment of systemic inflammatory rheumatic diseases during pregnancy and lactation. Autoimmun Rev, 15(10):955-963
- Schaefer C, et al. 2015. Immunosuppression, rheumatic diseases, multiple sclerosis, and Wilson's disease: Leflunomide. In: Drugs during pregnancy and lactation: Treatment options and risk assessment, 3rd ed (pp 362-363)(pp 658-659). London: Academic Press
- Viktil KK, et al. 2012. Outcomes after anti-rheumatic drug use before and during pregnancy: a cohort study among 150,000 pregnant women and expectant fathers. Scand J Rheumatol, 41(3):196-201
- 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. Aug;71:101-107

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(®Leflunomide (Arava

Selected References

- Anderson PO. 2021. Monoclonal antibodies during breastfeeding. *Breastfeed Med*, 16(8):591-593
- Belichón I, et al. 2022. Implementation of Recommendations for the Management of Psoriasis During Preconception, Pregnancy, Postpartum, Breastfeeding, and Perinatal Care. *Actas Dermosifiliogr*. 113(7):666-673
- Beltagy A, et al. 2021. Biologics During Pregnancy and Breastfeeding Among Women with Rheumatic Diseases: Safety Clinical Evidence on the Road. *Front Pharmacol*. 12:621247
- Cimzia Prescribing Information. Accessed January 22022
- Clowse ME, et al. 2018. Pregnancy Outcomes after Exposure to Certolizumab Pegol: Updated Results from a Pharmacovigilance Safety Database. *Arthritis Rheumatol*, 70(9):1399-1407
- Clowse MEB, et al. 2017. Minimal to no transfer of certolizumab pegol into breast milk: results from CRADLE, a prospective, postmarketing, multicentre, pharmacokinetic study. *Ann Rheum Dis*, 76:1890-1896
- Clowse M, et al. 2022. Pharmacovigilance pregnancy data in a large population of patients with chronic inflammatory disease exposed to certolizumab pegol. *Ther Adv Musculoskelet*. 14:1759720X221087650
- Förger F, et al. 2016. Certolizumab treatment during late pregnancy in patients with rheumatic diseases: Low drug levels in cord blood but possible risk for maternal infections. A case series of 13 patients. *Joint Bone Spine*, 83:341-343
- Habal FM and Huang VW. 2012. Review article: a decision-making algorithm for the management of pregnancy in the inflammatory bowel disease patient. *Aliment Pharmacol Ther*, 35(5):501-15
- Khan N, et al. 2014. Safety of anti-TNF therapy in inflammatory bowel disease during pregnancy. *Expert Opin Drug Saf*, 13 (12):1699-708
- Lambiase S, et al. 2022. Certolizumab pegol in pregnant and breastfeeding psoriatic patients. *Ital J Dermatol Venerol*. 157:383-34
- Mahadevan U, et al. 2011. The London Position Statement of the World Congress of Gastroenterology on Biological Therapy for IBD with the European Crohn's and Colitis Organization: pregnancy and pediatrics. *Am J Gastroenterol*, 106 (2):214-23
- Mahadevan U, et al. 2012. PIANO: A 1000 patient prospective registry of pregnancy outcomes in women with IBD exposed to immunomodulators and biologic therapy. *Gastroenterology*, 142(Suppl 1):S149. Abstract 865
- Mahadevan U, et al. 2017. Drug Safety and Risk of Adverse Outcomes for Pregnant Patients with Inflammatory Bowel Disease. *Gastroenterology*, 152(2):451-462.e452
- Mahadevan U, et al. 2021. Pregnancy and Neonatal Outcomes After Fetal Exposure to Biologics and Thiopurines Among Women with Inflammatory Bowel Disease. *Gastroenterology*, 160 (4):1131-1139
- Mariette X, et al. 2017. Lack of placental transfer of certolizumab pegol during pregnancy: results from CRIB, a prospective, postmarketing, pharmacokinetic study. *Ann Rheum Dis*, 0:1-6
- Membrive-Jiménez C, et al. 2023. Safety and effectiveness of bDMARDs during pregnancy in patients with rheumatic diseases: Real-world data from the BIOBADASER registry. *Reumatol Clin (Engl Ed)*. 19:500-6

- Oussalah A, et al. 2009. Certolizumab use in pregnancy. Gut, 58 (4):608
- Prieto-Peña D, et al. 2021. Efficacy and safety of certolizumabpegol in pregnant women with uveitis. Recommendations on the management with immunosuppressive and biologic therapies in uveitis during pregnancy. Clin Exp Rheumatol, 39:105-14
- Romanowska-Próchnicka K, et al. 2021. The Role of TNF-a and Anti-TNF-a Agents during Preconception, Pregnancy, and Breastfeeding. Int J Mol Sci. 22(6):2922
- Russell MD, et al. 2023. British Society for Rheumatology guideline on prescribing drugs in pregnancy and breastfeeding: Immunomodulatory anti-rheumatic drugs and corticosteroids. Rheumatology (Oxford). 62:e48-e88
- Sammaritano LR, et al. 2020. 2020 American College of Rheumatology Guideline for the Management of Reproductive Health in Rheumatic and Musculoskeletal Diseases. Arthritis Rheumatol, 72:529-56
- Shimada H, et al. 2019. Effect of biologic disease-modifying anti-rheumatic drugs for patients with rheumatoid arthritis who hope to become mothers. Rheumatol. 38 (5):1453-1458
- Strain J, et al. 2021. Certolizumab Pegol in Plaque Psoriasis: Considerations for Pregnancy. Skin Therapy. 26(2):1-5
- Thatiparthi A, et al. 2021. Biologic treatment algorithms for moderate-to-severe psoriasis with comorbid conditions and special populations: A review. Am J Clin Dermatol. 22:425-42
- Wakefield I, et al. 2011. The use of surrogate antibodies to evaluate the developmental and reproductive toxicity potential of an anti-TNF alpha PEGylated Fab' monoclonal antibody. Toxicol Sci, 122(1):170-6
- Weber-Schoendorfer C; network of French pharmacovigilance centres, et al. 2015. Pregnancy outcome after TNF-α inhibitor therapy during the first trimester: a prospective multicentre cohort study. Br J Clin Pharmacol, 80 (4):727-39
- Wolf D and Mahadevan U. 2010. Certolizumab use in pregnancy: low levels detected in cord blood. Arthritis Rheum [abstract], 62Suppl10:718

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:Selected References

- Bashore RA, et al. 1981. Heroin addiction and pregnancy. W J Med 134(6):506-14
- Broussard CS, et al. 2011. Maternal treatment with opioid analgesics and risk for birth defects. Am J Obstet Gynecol 204(4):314.e1-314.e11
- Cole FS, et al. 2017. The genomics of neonatal abstinence syndrome. Front Pediatr 5:176
- Committee on Drugs, American Academy of Pediatrics. 2001. The transfer of drugs and other chemicals into human milk. Pediatrics 108:776-89
- Daud AN, et al. 2015. P-glycoprotein-mediated drug interactions in pregnancy and changes in the risk of congenital anomalies: a case-reference study. Drug Safety 38(7):651-659
- Fajemirokun-Odukeyi O, et al. 2006. Pregnancy outcome in women who use opiates. Eur J Obstet Gynecol Reprod Biol 126(2):170-175
- Geng F, et al. 2018. Long-term effects of prenatal drug exposure on the neural correlates of memory at encoding and retrieval. Neurotoxicol Teratol 65:70-77
- Interrante JD, et al. 2017. Risk comparison for prenatal use of analgesics and selected birth defects, National Birth Defects Prevention Study 1997-2011. Annals of Epidemiology 27(10):645-653.e2
- Keegan J, et al. Addiction in pregnancy. J Addict Dis 29(2):175-91
- Ko JY, et al. 2017. CDC Grand Rounds: Public health strategies to prevent neonatal abstinence syndrome. MMWR Morb Mortal Wkly Rep Mar 10;66(9):242-245
- Lee SJ, et al. 2019. Neurodevelopmental outcomes of children born to opioid-dependent mothers: a systematic review and meta-analysis. Acad Pediatr S1876-2859(19)30457-7
- Lind JN, et al. 2017. Maternal use of opioids during pregnancy and congenital malformations: a systematic review. Pediatrics 139(6):e20164131
- Little BB, et al. 1990. Maternal and fetal effects of heroin addiction during pregnancy. J Reprod Med 35:159-62
- Nazmara Z, et al. 2020. Correlation between protamine-2 and miRNA-122 in sperm from heroin-addicted men: a case-control study. Urol J 28;17(6):638-644
- Nygaard E, et al. 2017. Cognitive function of youths born to mothers with opioid and polysubstance abuse problems during pregnancy. Chil Neuropsychol 23(2):159-187
- Oei JI. 2018. Adult consequences of prenatal drug exposure. Intern Med J 48(1):25-31
- Ostrea EM, Chavez CJ. 1979. Perinatal problems (excluding neonatal withdrawal) in maternal drug addiction: a study of 830 cases. J Pediatr 94:292-5
- Peterson BS, et al. 2020. Associations of maternal prenatal drug abuse with measures of newborn brain structure, tissue organization, and metabolite concentrations. JAMA Pediatr 174(9):831-842
- Stone ML, et al. 1971. Narcotic addiction in pregnancy. Am J Obstet Gynecol 109:716-23
- Stover MW, Davis JM. 2015. Opioids in pregnancy and neonatal abstinence syndrome. Semin Perinatol 39(7):561-5
- Thaithumyanon P, et al. 2005. Perinatal effects of amphetamine and heroin use during pregnancy on the mother and infant. J Med Assoc Thai 88(11):1506-13
- Vella, A., Savona-Ventura, C., & Mahmood, T. 2023. Harmful effects of opioid use in pregnancy: A scientific review commissioned by the European Board and College of obstetrics and gynaecology (EBCOG). Eur J Obstet Gynecol Reprod Biol, 286, 70-75

(®) Leflunomide (Arava)

:Selected References

- Aharon D. 1998. Pharmacology of leukotriene receptor antagonist. American Journal of Respirator Critical Care Medicine, 157; 214-219.
- American College of Obstetricians and Gynecologists (ACOG) and The American College of Allergy, Asthma and Immunology (ACAAI). 2000. The use of newer asthma and allergy medications during pregnancy. Ann Allergy Asthma Immunol, 84:475-480.
- Bakhireva LN, et al. 2007. Safety of leukotriene receptor antagonists in pregnancy. Journal of Allergy and Clinical Immunology, 119; 618-625.
- Cavero-Carbonell C, et al. 2017. Fetal exposure to montelukast and congenital anomalies: a population based study in Denmark. Birth Defects Res, 109(6):452-459.
- Datta P, et al. 2017. Transfer of montelukast into human milk during lactation. Breastfeed Med, 12:54-57.
- Hatakeyama S, et al. 2022. The safety of pranlukast and montelukast during the first trimester of pregnancy: a prospective, two-centered cohort study in Japan. Congenit Anom (Kyoto), 62(4):161-168.
- Merck Sharp y Dohme Corp. 2022. Etiquetado de productos Singulair. <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=8c166755-7711-4df9-d689-8836a1a70885>
- Nelsen LM et al. 2012. Congenital malformations among infants born to women receiving montelukast, inhaled corticosteroids, and other asthma medications. J Allergy Clin Immunol, 129(1):251-254.e1-6.
- Sarkar M, et al. 2009. Montelukast use during pregnancy: a multicentre, prospective, comparative study of infant outcomes Eur J Clin Pharmacol, 65(12):1259-1264.

(®) Leflunomide (Arava)

:Selected References

- Briggs GG, et al. 2017. Drugs in pregnancy and lactation: a reference guide to fetal and neonatal risk. Eleventh Edition. Philadelphia, PA: Wolters Kluwer
- Committee on Drugs, American Academy of Pediatrics. 2001. The transfer of drugs and other chemicals into human breast milk. Pediatrics. 108:776-789
- Egerman, et al. 1992. The tetracyclines. Obstet Gynecol Clin NA. 19(3):551-561
- Genot MT, et al. 1970. Effect of administration of tetracycline on teeth. J Oral Med. 25:75-79
- Gilman AG, et al. (Eds). 1985. Goodman and Gilman's The Pharmacological Basis of Therapeutics. Seventh Edition. Macmillan, New York
- Kline, et al. 1964. Transplacental effect of tetracycline on teeth. JAMA. 188:178
- Kutscher, et al. 1966. Discoloration of deciduous teeth induced by administration of tetracycline antepartum. Am J Obstet Gynecol. 96:291-292
- Muanda FT, Sheehy O, Bérard A. 2017. Use of antibiotics during pregnancy and the risk of major congenital malformations: a population based cohort study. Br J Clin Pharmacol. Nov;83(11):2557-2571
- O'Rahilly R and Mueller F. 1992. Human Embryology & Teratology. New York: Wiley-Liss
- The WHO Working Group, Bennet, PN (ed). 1988. Drugs and Human Lactation. New York: Elsevier
- Vennila V, et al. 2014. Tetracycline-induced discoloration of deciduous teeth: case series. J Int Oral Health 6(3): 115-11

