

Pegvaliase (Palynziq®)

Selected References:

- American Academy of Pediatrics Committee on Genetics. 2008. Maternal phenylketonuria. *Pediatrics* 122:445–449.
- American College of Obstetricians and Gynecologists Committee on Genetics. 2020. Management of women with phenylalanine hydroxylase deficiency (phenylketonuria). *Obstet Gynec*, 135(4):e167-e170.
- Bier C, et al. 2024. Outcomes in 14 live births resulting from Pegvaliase-treated pregnancies in PKU-affected females. *Mol Genet Metab*, 141(3):108152.
- BioMarin Pharmaceutical Inc. Palynziq medication label. Available at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=6dba844a-db02-44f8-8593-ce497ed9406c&type=display>. Accessed 27 October 2025.
- Cunningham A, et al. 2023. Nutrition management of PKU with pegvaliase therapy: Update of the web-based PKU nutrition management guideline recommendations. *Orphanet J Rare Dis*, 18:155.
- Fisch RO, et al. 1981 Semen studies on phenylketonurics. *Biochem Med*, 26(3):427434. Kopesky JJ, et al. 2024. Successful outcomes with continued pegvaliase-pqpz treatment throughout pregnancy and lactation in a PKU patient. *Mol Genet Metab*, 141:18.
- Levy HL, Waisbren SE. 1983. Effects of untreated maternal phenylketonuria and hyperphenylalaninemia on the fetus. *N Engl J Med*, 309:1269-1274.
- Rohr F, et al. 2020. Discontinuation of pegvaliase therapy during maternal PKU pregnancy and postnatal breastfeeding: A case report. *Mol Genet Metab Rep*, 22:100555.
- Rohr F, et al. 2022. Reinstitution of pegvaliase therapy during lactation. *Mol Genet Metab Rep*, 33:100938.
- Teissier R, et al. 2012. Maternal phenylketonuria: low phenylalaninemia might increase the risk of intra uterine growth retardation. *J Inherit Metab Dis*, 35(6):993-999.
- U.S. Food and Drug Administration Center for Drug Evaluation and Research. Active Risk Identification and Assessment (ARIA) Sufficiency Memo for Pregnancy Safety Concerns. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/761079Orig1s000OtherR.pdf. Accessed 27 October 2025.
- Waisbren SE, et al. 2015. Maternal phenylketonuria: long-term outcomes in offspring and post-pregnancy maternal characteristics. *JIMD Rep*, 21:23-33.

Mga Tanong? Tumawag sa 866.626.6847 | Mag-text sa 855.999.3525 | Mag-email o Makipag-chat sa MotherToBaby.org.

Disclaimer: MotherToBaby Fact Sheets are meant for general information purposes and should not replace the advice of your health care provider. MotherToBaby is a service of the non-profit Organization of Teratology Information Specialists (OTIS). Copyright by OTIS, March 1, 2026.

Pegvaliase (Palynziq®)

Selected References:

- Anderson KN, et al. 2020. ADHD medication use during pregnancy and risk for selected birth defects: National Birth Defects Prevention Study, 1998-2011. *J Atten Dis.* 24(3):479-489
- Bang Madsen K, et al. 2025. In utero exposure to methylphenidate, amphetamines and atomoxetine and offspring neurodevelopmental disorders – a population-based cohort study and meta-analysis. *Molecular psychiatry*, 30(9), 3885–3894.
- Benassayag Kaduri, N, et al. 2024. Amphetamine use for attention deficit hyperactive disorder during breastfeeding and children’s neurodevelopmental outcomes: A pilot study. *Psychiatry research*, 339, 116047.
- Cohen JM, et al. 2017. Placental complications associated with psychostimulant use in pregnancy. *Obstet Gynecol.* 130(6):1192-201.
- Eriksson M, et al. 1981. Amphetamine addiction and pregnancy II. Pregnancy, delivery, and the neonatal period. Socio-medical aspects. *Acta Obstet Gynecol Scand* 60:253-259.
- Food and Drug Administration. 2017. Adderall® CII. 2017. Accessed from https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/011522s043lbl.pdf.
- Food and Drug Administration. 2013. Highlights of Prescribing Information – Adderall XR. Accessed from https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/021303s026lbl.pdf.
- Garey JD, et al. 2020. Teratogen update: Amphetamines. *Birth Defects Res.* 112(15):1171-1182.
- Hasan SA, et al. 2026. Prescription Stimulant Continuation in Pregnancy and Birth Outcomes. *Journal of attention disorders*, 30(3), 315–328.
- Huybrechts KF, et al. 2018. Association Between Methylphenidate and Amphetamine Use in Pregnancy and Risk of Congenital Malformations: A Cohort Study From the International Pregnancy Safety Study Consortium. *JAMA Psychiatry.* 75(2):167-175.
- Ilett KF, et al. 2007. Transfer of dexamphetamine into breast milk during treatment for attention deficit hyperactivity disorder. *Br J Clin Pharmacol*, 63(3):371-375.
- Newport DJ, et al. 2016. Prenatal psychostimulant and antidepressant exposure and risk of hypertensive disorders of pregnancy. *J Clin Psychiatry.* 77(11):1538-45.
- Norby U, et al. 2017. Perinatal outcomes after treatment with ADHD medication during pregnancy. *Pediatrics* 140(6).
- Öhman I, et al. 2015. Narcolepsy treated with racemic amphetamine during pregnancy and breastfeeding. *J Hum Lact* 31:374-6.
- Pham MN, et al. 2022. The adverse association between stimulant use for attention deficit hyperactivity disorder (ADHD) and semen parameters. *Andrologia*, 54(2), e14315.
- Poulton AS, et al. 2018. Perinatal outcomes of women diagnosed with attention-deficit/hyperactivity disorder: An Australian population-based cohort study. *CNS Drugs* 32(4):377-386.
- Rose SJ, et al. 2020. Amphetamine-dextroamphetamine and pregnancy: neonatal outcomes after prenatal

prescription mixed amphetamine exposure. J Attention Dis. 25(9): 1295-1301.

- Russell DJ, et al. 2024. Investigating maternal and neonatal health outcomes associated with continuing or ceasing dexamphetamine treatment for women with attention-deficit hyperactivity disorder during pregnancy: a retrospective cohort study. Archives of women's mental health. 27(5), 785-94.
- Srinivas C, et al. 2025. Attention-Deficit/Hyperactivity Disorder Medication Use in Pregnancy and Risk of Preterm Birth: A Population-Based Cohort Study. Paediatric and perinatal epidemiology, 10.1111/ppe.70031.
- Steiner E et al. 1984. Amphetamine secretion in breast milk. Eur J Clin Pharmacol 27:123-4.
- Suarez EA, et al. 2024. Prescription Stimulant Use During Pregnancy and Risk of Neurodevelopmental Disorders in Children. JAMA psychiatry, 81(5), 477-488.
- Szpunar MJ, et al. 2023. Risk of Major Malformations in Infants After First-Trimester Exposure to Stimulants: Results From the Massachusetts General Hospital National Pregnancy Registry for Psychiatric Medications. Journal of clinical psychopharmacology, 43(4), 326-332.

Mga Tanong? Tumawag sa 866.626.6847 | Mag-text sa 855.999.3525 | Mag-email o Makipag-chat sa [MotherToBaby.org](https://www.MotherToBaby.org).

Disclaimer: MotherToBaby Fact Sheets are meant for general information purposes and should not replace the advice of your health care provider. MotherToBaby is a service of the non-profit Organization of Teratology Information Specialists (OTIS). Copyright by OTIS, March 1, 2026.

Pegvaliase (Palynziq®)

Selected References:

- Ahmad MK, et al. 2010. Withania somnifera improves semen quality by regulating reproductive hormone levels and oxidative stress in seminal plasma of infertile males. Fertil Steril, 94(3), 989-996.
- Ali H, et al. 2017. Effect of maternal antenatal and newborn supplementation with vitamin A on cognitive development of school-aged children in rural Bangladesh: a follow-up of a placebo-controlled, randomized trial. Am J Clin Nutr, 106(1), 77-87.
- American College of Obstetricians and Gynecologists (ACOG). (n.d.). Nutrition during pregnancy. ACOG. Retrieved May 4, 2025.
- Beurskens LW, et al. 2013. Dietary vitamin A intake below the recommended daily intake during pregnancy and the risk of congenital diaphragmatic hernia in the offspring. Birth Defects Res A Clin Mol Teratol, 97(1), 60-66.

- Botto LD, et al. 2001. Vitamin A and cardiac outflow tract defects. *Epidemiology*, 12, 491–496.
- Chameli G & Mukherjee KL. 1988. Relationship between maternal serum vitamin A and vitamin A status of the corresponding fetuses. *J Trop Pediatr*, 34(6), 313–315.
- Christian P, et al. 2013. Effects of vitamin A and beta-carotene supplementation on birth size and length of gestation in rural Bangladesh: a cluster-randomized trial. *Am J Clin Nutr*, 97(1), 188–194.
- Clagett-Dame M & Knutson D. 2011. Vitamin A in reproduction and development. *Nutrients*, 3(4), 385–428.
- Darling AM, et al. 2017. Vitamin A and zinc supplementation among pregnant women to prevent placental malaria: a randomized, double-blind, placebo-controlled trial in Tanzania. *Am J Trop Med Hyg*, 96(4), 826–834.
- Fonseca BM, et al. 2023. Retinoic acid (all-trans) presents antioxidant properties within human ovary and reduces progesterone production by human granulosa cells. *Syst Biol Reprod Med*, 69(2), 129–141.
- Hamdy AM, et al. 2013. Maternal vitamin A deficiency during pregnancy and its relation with maternal and neonatal hemoglobin concentrations among poor Egyptian families. *ISRN Pediatr*, 652148.
- Huang Y & Zheng S. 2011. The effect of vitamin A deficiency during pregnancy on anorectal malformations. *J Pediatr Surg*, 46(7), 1400–1405.
- Institute of Medicine (US) Panel on Micronutrients. 2001. Dietary reference intakes for vitamin A, vitamin K, arsenic, boron, chromium, copper, iodine, iron, manganese, molybdenum, nickel, silicon, vanadium, and zinc. Washington (DC): National Academies Press (US). Available from: <https://www.ncbi.nlm.nih.gov/books/NBK222318/>.
- Ishikawa Y, et al. 2016. Prenatal vitamin A supplementation associated with adverse child behavior at 3 years in a prospective birth cohort in Japan. *Pediatr Int*, 58(9), 855–861.
- Mastroiacovo P, et al. 1999. High vitamin A intake in early pregnancy and major malformations: a multicenter prospective controlled study. *Teratology*, 59(1), 7–11.
- Mills JL, et al. 1997. Vitamin A and birth defects. *Am J Obstet Gynecol*, 177(1), 31–36.
- Panth M, et al. 1990. Effect of vitamin A supplementation on haemoglobin and vitamin A levels during pregnancy. *Br J Nutr*, 64(2), 351–358.
- Pitchik HO, et al. 2018. Prenatal nutrition, stimulation, and exposure to punishment are associated with early child motor, cognitive, language, and socioemotional development in Dar es Salaam, Tanzania. *Child Care Health Dev*, 44(6), 841–849.
- Sakurai T, et al. 2005. Fat-soluble and water-soluble vitamin contents of breast milk from Japanese women. *J Nutr Sci Vitaminol*, 51(4), 239–247.
- Shaw GM, et al. 1997. Periconceptional intake of vitamin A among women and risk of neural tube defect-affected pregnancies. *Teratology*, 55, 132–133.

Mga Tanong? Tumawag sa 866.626.6847 | Mag-text sa 855.999.3525 | Mag-email o Makipag-chat sa [MotherToBaby.org](https://www.mothertobaby.org).

Disclaimer: MotherToBaby Fact Sheets are meant for general information purposes and should not replace the advice of your health care provider. MotherToBaby is a service of the non-profit Organization of Teratology Information Specialists (OTIS). Copyright by OTIS, March 1, 2026.

Pegvaliase (Palynziq®)

Selected References:

- Adhikari EH. 2026. Diagnosis and Management of Syphilis in Pregnancy. *Obstet Gynecol.* 147(3):323-35.
- American College of Obstetricians and Gynecologists. 2024. Screening for syphilis in pregnancy. <https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2024/04/screening-for-syphilis-in-pregnancy/>. [Accessed 03/2026].
- Appak O, et al. 2019. [A case of congenital syphilis and prozone phenomenon]. *Mikrobiyol Bul* 53(3): 336-342. Article in Turkish with English abstract.
- Brookings C, et al. 2013. Sexually transmitted infections and sexual function in relation to male fertility. *Korean J Urol.* 54(3):149-56.
- Centers for Disease Control and Prevention. 2025. About syphilis. Centers for Disease Control and Prevention <https://www.cdc.gov/syphilis/about/index.html>. [Accessed 03/2026]
- Centers for Disease Control and Prevention. 2025. STD facts – congenital syphilis. <https://www.cdc.gov/syphilis/about/about-congenital-syphilis.html>. [Accessed 03/2026]
- Chevalier FJ, et al. 2025. Syphilis: A Review. *JAMA.* 334(21):1927-40. Erratum in: *JAMA.* 334(21):1955.
- da Silva HBM, et al. 2024. Syphilis in pregnancy and adverse birth outcomes: A nationwide longitudinal study in Brazil. *Int J Gynaecol Obstet.* 166(1): 80-9.
- Desjardins AA, et al. 2025. FIGO Committee on Infections During Pregnancy and FIGO Committee on Health Systems Strengthening. Syphilis in pregnancy: A practical guide for prenatal care providers. *Int J Gynaecol Obstet.* 171(2):601-10.
- Gulersen M, et al. 2023. Risk factors and adverse outcomes associated with syphilis infection during pregnancy. *Am J Obstet Gynecol MFM.* 5(6):100957. Hegde A, et al. 2023. Congenital syphilis: a rare presentation of a forgotten infection. *J Infect Dev Ctries* 17(1): 135-138.
- Kimberlin DW, et al. 2021. Committee on Infectious Diseases, American Academy of Pediatrics. Red Book: 2021–2024 Report of the Committee on Infectious Diseases. American Academy of Pediatrics; Itasca, IL, USA.
- Mascola L, et al. 1985. Congenital syphilis revisited. *Am J Dis Child* 139:575-80.
- Mavrov GI, Goubenko TV. 2001. Clinical and epidemiological features of syphilis in pregnant women: the course and outcome of pregnancy. *Gynecol Obstet Invest;* 52:114-8.
- Mayo Foundation for Medical Education and Research. 2024. Syphilis. Mayo Clinic. <https://www.mayoclinic.org/diseases-conditions/syphilis/symptoms-causes/syc-20351756>. [Accessed 03/2026]
- Office on Women's Health. 2024. Sexually transmitted infections, pregnancy, and breastfeeding. U.S. Department of Health and Human Services. [Accessed 03/2026]. <https://womenshealth.gov/a-z-topics/stis-pregnancy-and-breastfeeding>
- Papp JR, et al. 2024. CDC Laboratory Recommendations for Syphilis Testing, United States, 2024.

MMWR Recomm Rep. 73(1):1–32.

- Peeling RW, et al. 2023. Syphilis. Lancet. 402(10398):336-46.
- Rac MW, et al. 2017. Syphilis during pregnancy: a preventable threat to maternal-fetal health. Am J Obstet Gynecol; 216(4): 352-363.
- Sankaran D, et al. 2023. Congenital Syphilis-An Illustrative Review. Children (Basel).; 10(8):1310.
- Schlueter A, et al. 2022 Adverse pregnancy outcomes associated with maternal syphilis infection, The Journal of Maternal-Fetal & Neonatal Medicine, 35 (25): 5828-5833,
- Stafford IA, et al. 2024. Syphilis Complicating Pregnancy and Congenital Syphilis. N Engl J Med. 390(3):242-253.
- Verghese VP, et al. 2018. Early Childhood Neurodevelopmental Outcomes in Infants Exposed to Infectious Syphilis In Utero. Pediatr Infect Dis J; 37(6):576-579.
- Wan Z, et al. 2020. Maternal syphilis treatment and pregnancy outcomes: a retrospective study in Jiangxi province, China. BMC Pregnancy Childbirth. 20:648

Mga Tanong? Tumawag sa 866.626.6847 | Mag-text sa 855.999.3525 | Mag-email o Makipag-chat sa [MotherToBaby.org](https://www.MotherToBaby.org).

Disclaimer: MotherToBaby Fact Sheets are meant for general information purposes and should not replace the advice of your health care provider. MotherToBaby is a service of the non-profit Organization of Teratology Information Specialists (OTIS). Copyright by OTIS, March 1, 2026.

Pegvaliase (Palynziq®)

Selected References:

- Andersson NW et al 2021. Evaluation of topical corticosteroids use in pregnancy and risk of newborns being small for gestational age and having low birth weight. JAMA Dermatol 157(7): 788-795. Doi10.1001/jamadermatol.2021.1090.
- Chan TC, et al. 2020. Taiwanese Dermatological Association consensus for the management of atopic dermatitis: A 2020 update. Journal of the Formosan Medical Association.
- Chi CC et al. 2013. Pregnancy outcomes after maternal exposure to topical corticosteroids: a UK population-

based cohort study. JAMA Dermatol. 149(11):1274-1280.

- Chi CC, et al. 2015. Safety of topical corticosteroids in pregnancy. Cochrane Database Syst Rev. (10):CD007346.
- Chi CC, et al. 2016. Safety of Topical Corticosteroids in Pregnancy. JAMA Dermatol. 152(8):934-5.
- Chi CC, et al. 2017. Updated evidence-based (S2e) European Dermatology Forum guideline on topical corticosteroids in pregnancy. J Eur Acad Dermatol Venereol. 31(5):761-773.
- Hamann CR, et al. 2018. Pregnancy complications, treatment characteristics and birth outcomes in women with atopic dermatitis in Denmark. J Eur Acad Dermatol Venereol. [Epub ahead of print].
- Mygind H et al 2002. Risk of intrauterine growth retardation, malformations and other birth outcomes in children after topical use of corticosteroid pregnancy. Acta Obstet Gynecol Scand 81(3):234-239.
- Stacey SK, McEleney M. 2021. Topical Corticosteroids: Choice and Application. Am Fam Physician; 103(6):337-343.
- Tyler KH. 2015. Dermatologic therapy in pregnancy. Clin Obstet Gynecol. 58(1):112-8.
- Vestergaard C, et al. 2019. European task force on atopic dermatitis position paper: treatment of parental atopic dermatitis during preconception, pregnancy and lactation period. Journal of the European Academy of Dermatology and Venereology, 33(9): 1644-1659

Mga Tanong? Tumawag sa 866.626.6847 | Mag-text sa 855.999.3525 | Mag-email o Makipag-chat sa [MotherToBaby.org](https://www.MotherToBaby.org).

Disclaimer: MotherToBaby Fact Sheets are meant for general information purposes and should not replace the advice of your health care provider. MotherToBaby is a service of the non-profit Organization of Teratology Information Specialists (OTIS). Copyright by OTIS, March 1, 2026.