



Center for
Research, Education, Quality & Safety

FDA Alerts and Label Changes – What Neonatologists Need to Know

Abdel-Rahman, S. M., Paul, I. M., Delmore, P., Chen, J. Y., Mills, M., & Greenberg, R. G. (2020). Validation and human factor analysis study of an infant weight estimation device. *BMC pediatrics*, 20(1), 1-8.

Burke, C. W. (2019, July 1). The Common, yet Unspoken, Practice of Off-Label Drug Prescribing. Retrieved from <https://www.biospace.com/article/the-common-yet-unspoken-practice-of-off-label-drug-prescribing/>.

Center for Drug Evaluation and Research. (n.d.). General Clinical Pharmacology Considerations for Neonatal Studies for. Retrieved from <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-clinical-pharmacology-considerations-neonatal-studies-drugs-and-biological-products-guidance>

Center for Drug Evaluation and Research. (n.d.). Population Pharmacokinetics. Retrieved from <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/population-pharmacokinetics>

Christensen, J. (2016, November 14). FDA spotlights unapproved use of drugs, medical devices. Retrieved from <https://www.cnn.com/2016/11/11/health/fda-hearings-off-label-drugs/index.html>.

Dai, X., & Zhou, Z. H. (2018). Structure of the herpes simplex virus 1 capsid with associated tegument protein complexes. *Science*, 360(6384), eaao7298.

Hsieh, E. M., Hornik, C. P., Clark, R. H., Laughon, M. M., Benjamin Jr, D. K., & Smith, P. B. (2014). Medication use in the neonatal intensive care unit. *American journal of perinatology*, 31(09), 811-822.

Merrem (meropenem for injection) IV. (n.d.). Retrieved from https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/050706Orig1s037ltr.pdf

Sampson, M. R., Bloom, B. T., Lenfestey, R. W., Harper, B., Kashuba, A. D., Anand, R., ... & Smith, P. B.



Center for
Research, Education, Quality & Safety

(2014). Population pharmacokinetics of intravenous acyclovir in preterm and term infants. *The Pediatric infectious disease journal*, 33(1), 42.

Smith, P. B., Cohen-Wolkowicz, M., Castro, L. M., Poindexter, B., Bidegain, M., Weitkamp, J. H., ... &

Burchfield, D. (2011). Population pharmacokinetics of meropenem in plasma and cerebrospinal fluid of infants with suspected or complicated intra-abdominal infections. *The Pediatric infectious disease journal*, 30(10), 844.

Stark, A., Childers, J., England, M., Clark, R. H., Laughon, M., Cohen-Wolkowicz, M., ... & Greenberg, R. G.

(2020). Dosing of Antimicrobials in the Neonatal Intensive Care Unit: Does Clinical Practice Reflect Pharmacokinetics-based Recommendations? *The Pediatric Infectious Disease Journal*.

Tremoulet, A., Le, J., Poindexter, B., Sullivan, J. E., Laughon, M., Delmore, P., ... & Benjamin, D. K. (2014).

Characterization of the population pharmacokinetics of ampicillin in neonates using an opportunistic study design. *Antimicrobial agents and chemotherapy*, 58(6), 3013-3020.

Wade, K. C., Benjamin Jr, D. K., Kaufman, D. A., Ward, R. M., Smith, P. B., Jayaraman, B., ... & Barrett, J. S.

(2009). Fluconazole dosing for the prevention or treatment of invasive candidiasis in young infants. *The Pediatric infectious disease journal*, 28(8), 717.