DRUG PROFILE

APPLICATION OF THERAPEUTIC MONOCLONAL ANTIBODIES AND FC FUSION PROTEINS IN PEDIATRICS

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Abstract: *The experience with the use of monoclonal antibodies and Fc fusion proteins in the pediatric age group is limited. The objective of this article is to review those factors impacting the clinical efficacy and safety of monoclonal antibodies and Fc fusion proteins in pediatric patients during drug development. Of the 68 monoclonal antibodies and Fc-fusion protein products, 20 products have approved indications in children. The number of children studied was approximately 2% to 70% of the sample size of adult studies carried out for the same indication. In general, pediatric dosing regimens were often based on body weight and weight tiered than the adult-dosing regimen. In conclusion, most monoclonal antibody and Fc-fusion protein products use weight-based dosing regimens for pediatric patients that differ from adult dosing.*

Keywords: *Pediatric dosing, Drug development, Fc-fusion proteins, Immunogenicity, Modelling and simulation, Monoclonal antibodies.*

Points to Remember

- ***Fewer studies in children as compared to adults mean that the last is not yet said regarding recommendations on drug dosing, side effects and safe use of mAb/Fc products in children.***
- ***The use of mAb/Fc products in lower-middle-income countries, including India, is low***
- ***Pediatricians need to be aware of newer mAb/Fc products licensed for use in pediatrics.***

References

1. US Food and Drug Administration. Immunogenicity Assessment for Therapeutic Protein Products. https://www.fda.gov/downloads/drugs/guidances/ucm338856.pdf. Accessed September 17, 2025.
2. US Food and Drug Administration. Guidance for Industry: Immunogenicity Testing of Therapeutic Protein Products-Developing and Validating Assays for AntiDrug Antibody Dectection. https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm629728.pdf. Accessed September 17, 2025.
3. Levy G. Pharmacologic targetmediated drug disposition. Clin Pharmacol Ther. 1994; 56:248252.
4. Mager DE, Jusko WJ. General pharmacokinetic model for drugs exhibiting targetmediated drug disposition. J Pharmacokin Pharmacodyn. 2001; 28: 507532.
5. US Food and Drug Administration. Guidance for Industry: Pediatric Rare Diseases-A Collaborative Approach for Drug Development Using Gaucher Disease as a Model. https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM587660.pdf Published 2017. Accessed September 17, 2025.

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6. Liu XI, Dallmann A, Wang YM, Green DJ, Burnham JM, Chiang B, Wu P, Sheng M, Lu K, van den Anker JN, Burckart GJ. Monoclonal Antibodies and Fc-Fusion Proteins for Pediatric Use: Dosing, Immunogenicity, and Modeling and Simulation in Data Submitted to the US Food and Drug Administration. J Clin Pharmacol. 2019 Aug;59(8):1130-1143. doi: 10.1002/jcph.1406.
7. Bai S, Jorga K, Xin Y, Jin D, Zheng Y, Damico-Beyer LA, Gupta M, Tang M, Allison DE, Lu D, Zhang Y, Joshi A, Dresser MJ. A guide to rational dosing of monoclonal antibodies. Clin Pharmacokinet. 2012 Feb 1; 51(2):119-35.
8. BNF for children 2019-20. British Medical Association, Royal Pharmaceutical Society of Great Britain, Royal College of Paediatrics and Child Health, Neonatal and Paediatric Pharmacists Group. BMJ Group, Tavistock Square, London, WC1H 9JP, UK and Pharmaceutical Press Pharmaceutical Press is the publishing division of the Royal Pharmaceutical Society. 66-68 East Smithfield, London E1W1AW, UK. 2019.
9. IAP Drug Formulary 2024 with IAP Recommendations on Drug Therapy for Pediatric Illness. 6th ed. Eds Jeeson C Unni, Pallab Chatterjee. A project of IAP CMIC, Pixel Studio, Cochin, 2014.
10. Wang YM, Wang J, Hon YY, Zhou L, Fang L, Ahn HY. Evaluating and reporting the immunogenicity impacts for biological products-a clinical pharmacology perspective. AAPS J. 2016; 18:395403.