

# Best Pharmaceuticals for Children Act (BPCA)

## Clindamycin



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Clindamycin is commonly used to treat serious infections in children. The effectiveness of the medication correlates directly with how long the concentration of clindamycin in the blood remains high enough to inhibit the growth of the pathogen of interest. However, variability in the drug's serum and tissue concentrations has been reported in obese patients, an increasingly important factor to consider in dosing as obesity rates rise in U.S. children.

### Studies

**Safety and Pharmacokinetics (PK) Study of Multiple-Dose Intravenous (IV) and Oral Clindamycin in Pediatric Subjects with BMI  $\geq$  85th Percentile (NICHD-2012-CLN01)** developed a comprehensive PK profile across the age spectrum to assess PK/pharmacodynamic relationships in pediatric patients. This prospective, open-label safety and PK study evaluated multiple doses of clindamycin (oral and IV) in overweight and obese children 2 years to 18 years of age. The study enrolled 23 participants. Additional clindamycin PK data from other NICHD studies were used to develop the population PK model, so that a total of 220 children contributed 420 PK samples to the analysis (including 187 PK samples from 95 overweight or obese children).

### Findings

- After accounting for differences in total body weight, obesity status did not explain additional interindividual variability in PK parameters ([PMID: 28137820](https://pubmed.ncbi.nlm.nih.gov/28137820/)).
- Overall, clindamycin was well tolerated in study participants.
- **Key Outcome:** Clindamycin may be dosed based on total body weight (max dose 2.7 g/day) without the need to adjust the dose specifically for obese patients. As a result of this research, the U.S. Food and Drug Administration (FDA) updated the clindamycin label in 2020.

### Resources

- NICHD's [Data and Specimen Hub](https://dash.nichd.nih.gov/Study/228258) provides an overview of the study population and, for registered users, free access to datasets, study reports and documentation.
  - <https://dash.nichd.nih.gov/Study/228258>
- ClinicalTrials.gov: <https://clinicaltrials.gov/ct2/show/NCT01744730>
- FDA Label: Injection - <https://bit.ly/2UUEcbl> Capsules - <https://bit.ly/2UPAK1Y>

**About BPCA:** The NICHD-led BPCA program at NIH helps advance pediatric drug research & development and improves information about and labeling for drugs used in children. The program identifies research gaps in pediatric therapeutics, prioritizes drugs in need of further study, supports research training, and sponsors clinical studies of prioritized drugs through the Pediatric Trials Network. Learn more at <https://www.nichd.nih.gov/BPCA>.



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