

Doxycycline



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Doxycycline is a tetracycline-class antimicrobial used to treat life-threatening infectious diseases, such as anthrax and Rocky Mountain spotted fever (RMSF) in children up to 8 years of age. Despite current literature, only 35% of U.S. healthcare providers report using the drug in patients in this age group with suspected RMSF. As a result of the following pediatric research, the U.S. Food and Drug Administration (FDA) updated the doxycycline label in 2020.

Studies

Pharmacokinetics (PK) of Understudied Drugs Administered to Children per Standard of Care (POP01), a multicenter, prospective study, enrolled participants through the Pediatric Trials Network under multiple drugs of interest, including doxycycline. POP01 gathered PK and safety data for understudied drugs in children younger than 21 years of age who received certain drugs per standard of care. A total of 47 participants receiving doxycycline contributed 74 plasma samples to the population PK analysis. Three participants were younger than 2 years of age; 11 were between 2 years and 8 years of age; and 33 participants were older than 8 years of age.

Findings

- There was no indication of tooth discoloration from data collected from 6 participants age 8 years or younger ([PMID: 31548185](#)).
- There were no serious, unexpected, suspected adverse reactions to doxycycline reported within 3 days of PK sampling.
- **Key Outcome:** Children between 2 years and 8 years of age can tolerate the same per kg dosing of oral and intravenous doxycycline as children older than 8 years of age without significant adverse outcomes. As a result of this research, the U.S. Food and Drug Administration (FDA) updated the label in 2020.

Resources

- NICHD's [Data and Specimen Hub](#) 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/19016>
- ClinicalTrials.gov: <https://clinicaltrials.gov/ct2/show/NCT01431326>
- FDA Label: Vibramycin - <https://bit.ly/3bE8x4Y> Acticlate - <https://bit.ly/39zkRCa> Doryx - <https://bit.ly/2UwY2L7>

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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