

Adacel[®] (tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine adsorbed) – New indication

- On January 9, 2023, the [FDA approved](#) Sanofi's [Adacel \(tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine adsorbed\)](#), for immunization during the third trimester of pregnancy to prevent pertussis in infants younger than 2 months of age.
- Adacel is also approved for the active booster immunization against tetanus, diphtheria, and pertussis in individuals 10 through 64 years of age.
- The effectiveness of Adacel immunization during the third trimester of pregnancy to prevent pertussis among infants younger than 2 months of age was assessed based on a re-analysis of the Adacel-relevant data from an observational study of Tdap vaccine effectiveness in the U.S. This matched case-control study included pertussis cases reported from 2011 through 2014 in infants born at ≥ 37 weeks gestation and ≥ 2 days old.
 - The vaccine effectiveness estimate was 88.0% (95% CI: 43.8, 97.4) for vaccination during the third trimester and ≥ 14 days before delivery.
- Published studies have reported diminished immune responses to pertussis antigens in DTaP-containing vaccines administered to infants whose mothers received Adacel during the third trimester of pregnancy compared with infants whose mothers did not receive Adacel during the third trimester of pregnancy. Whether the diminished immune responses observed in vaccinated infants whose mothers received Adacel during pregnancy result in diminished effectiveness of pertussis vaccination in infants is unknown.
- To prevent pertussis in infants younger than 2 months of age, Adacel should be administered as a single 0.5 mL intramuscular injection to pregnant individuals during the third trimester of pregnancy.
 - Refer to the Adacel drug label for administration recommendations for its other uses.