

RSV vaccines indicator

Safety of the intervention

Type, including severity, consequences and frequency of short- and long-term adverse events following vaccination

Adverse events after nirsevimab administration may include a rash, rash maculo-papular and rash papular. There may also be an injection site reaction including injection site pain, induration, edema and site swelling. Very rare cases of serious hypersensitivity reactions have been reported following nirsevimab administration, these reactions included urticaria, dyspnea, cyanosis, and/or hypotonia. [1](#)

Recipients of the maternal RSVPreF vaccine may experience injection site pain, which is mild to moderate. Systemic symptoms, including muscle pain and headaches may also occur. [2](#)

In clinical trials, serious adverse events included a numerical increase in preterm births in maternal vaccine recipients (this was not statistically significant overall, and available data are insufficient to establish or exclude a causal relationship between preterm birth and the vaccine). A numerical increase in hypertensive disorders of pregnancy were also observed among vaccine recipients (not statistically significant). In infants of vaccine recipients, low birth weight cases were higher compared to the placebo group (not statistically significant). Post-authorization safety evaluations from the first season of use in the US concluded that the RSVPreF vaccine is not associated with increased risk for preterm birth or SGA at birth. [3](#), [4](#)

Sources

1.

FDA-Approved drugs (2024). United States Food and Drug Administration (FDA) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761328s005lbl.pdf, accessed 20 June 2025).

2.

FDA-Approved drugs (2024). United States Food and Drug Administration (FDA) (<https://www.fda.gov/media/168889/download?attachment>, accessed 20 June 2025).

3.

Kampmann B, Madhi SA, Munjal I, Simões EAF, Pahud BA, Llapur C, et al. (2023). Bivalent prefusion F vaccine in pregnancy to prevent RSV illness in infants. *N Engl J Med.* 388:1451–64.

4.

DeSilva M (2024). RSVpreF vaccine, preterm birth, and small for gestational age at birth: preliminary results from the Vaccine Safety Datalink. ACIP meeting, October 2024 (<https://www.cdc.gov/acip/downloads/slides-2024-10-23-24/03-RSV-Mat-Peds-DeSilva-508.pdf>, accessed 20 June 2025).