

2 RSV VACCINATION OF PREGNANT PATIENTS

WHO QUALIFIES FOR RSV VACCINE?

32

WEEKS

to

36

WEEKS

All Pregnant Patients are Eligible to Receive a Single Dose of RSV Vaccine.

The approved interval for when to administer is during 32 to 36 weeks gestation.

If the patient has received RSV Vaccine during a previous pregnancy, an additional dose is not recommended at this time.

51% EFFICACY

Preventing medically attended RSV-associated lower respiratory tract disease in infants

56% EFFICACY

Preventing hospitalization for RSV-associated lower respiratory tract infection in infants (0-180 days)

ADMINISTRATION WINDOW



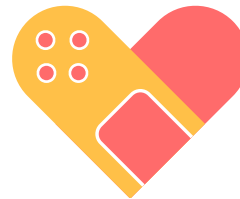
to



The ACIP Recommended Administration Window for RSV Vaccine to Pregnant Patients is:

September 1st through January 31st

CO-ADMINISTRATION WITH OTHER ROUTINE VACCINES



ROUTINE VACCINATIONS SUCH AS TDAP, INFLUENZA, AND COVID-19 CAN BE GIVEN AT THE SAME VISIT

CDC allows for simultaneous administration of routine vaccinations within the same visit under CDC's immunization general best practices.

RSV Vaccine can be given with Tdap, influenza, COVID-19, and other routine vaccinations without regards to timing and during the same visit.

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THE PATIENT RECEIVED RSV VACCINE DURING A PREVIOUS PREGNANCY:

ACIP currently only recommends a **single dose** of RSV Vaccine in pregnancy. Patients who received RSV vaccine during a previous pregnancy are not currently eligible for an additional dose. Infants should instead receive nirsevimab, the monoclonal antibody that offers protection against RSV.

RATES OF KEY ADVERSE EVENTS:

There were **no statistically significant differences** in key adverse events for RSV Vaccine compared to placebo in clinical trials.

Rates of events were (RSVpreF vs. placebo): Pre-eclampsia (1.8% vs. 1.4%), Gestational Hypertension (1.1% vs. 1.0%), and Premature Rupture of Membranes (0.4% vs. 0.4%).



SUMMARY OF PRETERM BIRTHS IN CLINICAL TRIALS

KEY POINTS OF PRETERM BIRTHS IN CLINICAL TRIALS

- For patients in the United States, the Preterm Birth rate was 5.7% in RSVpreF vs. 5.3% in Placebo (not statistically significant)
- There were no statistically significant findings for preterm births or low birth weights in vaccine vs. placebo groups when given at the ACIP-approved timing
- Most preterm births (91%) were late preterm at ≥ 34 weeks gestation
- Most preterm births occurred > 30 days after vaccination
- The preterm birth imbalance between RSVpreF and placebo was most prominent in patients located in South Africa

RATE OF PRETERM BIRTHS IN CLINICAL TRIALS VS BACKGROUND INCIDENCE

Clinical trials had multiple exclusion criteria resulting in selection of a population at lower risk of preterm birth than the general population. The overall preterm birth rate in trials (5.2%) was lower than the background incidence rate of preterm birth in the United States (~10%).



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