2 RSV VACCINATION OF PREGNANT PATIENTS

1 DOSE

One dose completes the series

WEEKS GESTATION

32 to 36

At time of administration

SEPTEMBER - JANUARY

RSVpreF administration to pregnant patients is recommended by ACIP September 1st through January 31st

Who is Recommended to Receive RSVpreF in Pregnancy?

ALL PREGNANT PATIENTS 32 TO 36 WEEKS GESTATION

All pregnant patients are recommended to receive RSVpreF. The approved interval for when to administer is during 32 to 36 weeks gestation.

NOTE: *The version of RSV vaccine approved in pregnancy is only manufactured by one company.*

51%

Efficacy against medically attended RSV-associated lower respiratory tract disease in infants

56%

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

Can Other Vaccines Be Coadministered in the Same Visit?

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

There is no available data on coadministration of RSVpreF in pregnant patients and other routine vaccinations. Coadministration data exists for RSVpreF and influenza vaccine in older adults.

CDC allows for simultaneous administration of routine vaccinations within the same visit under CDC's immunization general best practices. Healthcare providers can administer RSVpreF with Tdap, influenza, COVID-19, and other routine vaccinations without regards to timing and during the same visit.

RSV 1 2 3

MICIS
Maine Independent Clinical Information Service

2 RSV VACCINATION OF PREGNANT PATIENTS

ADVERSE EVENTS

There were no statistically significant differences in key adverse events for RSVpreF compared to placebo. 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%).

No inflammatory demyelinating events were reported in clinical trials with pregant patients, including no cases of Guillain-Barré Syndrome (GBS).

Intrauterine deaths were reported in 18 out of 7,357 participants, 10 (0.3%) in the RSVpreF group and 8 (0.2%) in the placebo group. There was no clear pathophysiologic pattern to the intrauterine deaths and they were a result of various conditions and presentations.

SUMMARY 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.

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%).

KEY POINTS OF PRETERM BIRTHS IN CLINICAL TRIALS

- 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
- For patients in the United States, preterm birth rate was 5.7% in RSVpreF vs. 5.3% in placebo

Outcomes in RSVpreF Phase III Clinical Trials

Preterm Births & Low Birth Weight*

	RSVpreF	Placebo
Preterm Birth (< 37 wks)	5.7% (95% CI 4.9%, 6.5%)	4.7% (95% CI 4.1%, 5.5%)
Late Preterm Birth (≥34 to < 37 wks)	5.0%	4.4%
Low Birth Weight (≤2500g)	5.1%	4.4%

Preterm Birth Based on Time From Vaccination*

	RSVpreF, n (%)	Placebo, n (%)
≤ 7 days	11 (5.5%)	13 (7.7%)
> 7 to ≤ 30 days	69 (34.4%)	58 (34.3%)
> 30 days	121 (60.2%)	98 (58%)

**The values above did not meet statistical significance*

SCAN HERE!

Maine Independent Clinical Information Service (MICIS)
Visit our website https://micismaine.org/ or scan the code for more information about our services

MICIS is administered by the Maine Medical Association with funding from Maine DHHS. MICIS does not accept compensation from pharmaceutical companies.

Disclaimer: These are general recommendations only; specific clinical decisions should be made by the treating healthcare provider based on an individual patient's clinical condition.

Information Adapted From:
Fleming-Dutra K. Evidence to Recommendations Framework Updates Pfizer Maternal RSVpreF Vaccine. Presented at Advisory Committee for Immunization Practices (ACIP) General Meeting; September 22, 2023; Atlanta, GA.

RSV 1 2 3

MICIS
Maine Independent Clinical Information Service

Version 1.0 October 2023