Healthcare Providers: RSV Immunization for Infants and Young Children

About Nirsevimab

Nirsevimab is an injectable monoclonal antibody that prevents severe RSV disease in infants and young children. Monoclonal antibodies do not activate the immune system, as would occur with infection or vaccination (active immunization). Rather, the antibodies themselves protect against disease (i.e., passive immunization).

Because nirsevimab does not activate the immune system, protection is likely most effective the weeks after nirsevimab is given and wanes over time. Nirsevimab does not provide long-term immunity to RSV disease but provides protection to infants when they are most at risk of getting severe RSV disease. As children get older, they are less likely to get severe symptoms from RSV infection.

Storage and Handling of Nirsevimab

Proper storage and handling of nirsevimab is essential to ensure it is effective in preventing RSV disease.

Nirsevimab is supplied as pre-filled syringes for one time use only. It comes in two doses:

- 50 mg/0.5 ml
- 100 mg/ml

The pre-filled syringes should be stored refrigerated between 36°F to 46°F (2°C to 8°C) and may be kept at room temperature 68°F to 77°F (20°C to 25°C) for a maximum of 8 hours. They should be stored in the original carton to protect from light until time of use. Do not freeze or expose to heat.

After removal from the refrigerator, they must be used within 8 hours or discarded. Do not use nirsevimab beyond the expiration date printed on the label.

Administering Nirsevimab

Route

Administer nirsevimab intramuscularly. The preferred site of administration is the anterolateral thigh region. Do not administer nirsevimab intravenously, intradermally, or subcutaneously.

Dosage

- Age less than 8 months
  - 50 mg for infants weighing <5 kg [<11 lb], administered as single dose
  - 100 mg for infants weighing ≥5 kg [≥11 lb] , administered as single dose
- Age 8 through 19 months:
  - 200 mg, administered as two 100 mg injections

See “Additional Considerations” in RSV Immunization Guidance for Infants and Young Children for more information on seasonal administration of nirsevimab.

Administration with Vaccine Products

Nirsevimab can be administered without regard to timing of routine childhood vaccines. This includes simultaneous administration (i.e., same clinic day) with vaccine products. No interval between nirsevimab and live vaccines (such as MMR and Varicella) is necessary.

Nirsevimab is not expected to interfere with the immune response to vaccine products. There is limited experience with administering nirsevimab with vaccine products. In clinical trials, when nirsevimab was given concomitantly with routine childhood vaccines, the safety and reactogenicity profile of the co-administered regimen was similar to the childhood vaccines given alone.

References

- Jones JM, Fleming-Dutra KE, Prill MM, et al. Use of Nirsevimab for the Prevention of Respiratory Syncytial Virus Disease Among Infants and Young Children: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023. MMWR Morb Mortal Wkly Rep 2023;72:920–925. DOI: http://dx.doi.org/10.15585/mmwr.mm7234a4 .
- Food and Drug Administration. Beyfortus (nirsevimab-alip) product label. Silver Spring, MD: US Department of Health and Human Services, Food and Drug Administration; 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761328s005lbl.pdf
- Food and Drug Administration: FDA Approves First Vaccine for Pregnant Individuals to Prevent RSV in Infants. Press Release. Silver Spring, MD: US Department of Health and Human Services, Food and Drug Administrations; 2023.
- Hamid S, Winn A, Parikh R, et al. Seasonality of Respiratory Syncytial Virus – United States, 2017-2023. MMWR Morb Mortal Wkly Rep. 2023 Apr 7;72(14):355-361. doi: 10.15585/mmwr.mm7214a1
- CDC RSV Surveillance & Research

Resources

Infant RSV Prevention At A Glance [3 pages]

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