



## FDA explains safety reporting for new RSV monoclonal antibody

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from the Food and Drug Administration

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The Food and Drug Administration (FDA) is encouraging health care providers to use the following approach to report adverse events and medication errors associated with the monoclonal antibody nirsevimab-alip (“nirsevimab,” Beyfortus), which recently was approved to protect infants and certain high-risk toddlers from respiratory syncytial virus (RSV):



- Adverse events or medication errors that occur with administration of nirsevimab alone should be reported to the MedWatch Adverse Event Reporting Program, <https://bit.ly/reporttoFDA>.
- Adverse events or medication errors that occur with co-administration of nirsevimab with a vaccine should be reported to the Vaccine Adverse Event Reporting System (VAERS) (<https://vaers.hhs.gov/index.html>). On the form, specify that the patient also received nirsevimab.

Nirsevimab is the first single-dose, long-acting recombinant monoclonal antibody approved by the FDA for the prevention of lower respiratory tract disease caused by RSV. Like vaccines, nirsevimab is used as a preventive measure. However, it is a therapeutic biologic, which impacts the way adverse events and medication errors are reported.

Many pediatric providers are aware of VAERS because of laws that require reporting for certain adverse events associated with U.S. licensed vaccines. Many providers, however, may not have experience with MedWatch, a voluntary reporting system that supports the FDA's postmarketing safety surveillance for drugs and therapeutic biologics. Due to the potential for reporting into both systems, the FDA will be monitoring adverse events and medication errors through MedWatch and VAERS.

Nirsevimab is indicated for neonates and infants born during or entering their first RSV season and children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season. Given the substantial impact of RSV on neonates and infants, the FDA anticipates widespread use of nirsevimab.

The safety and efficacy of nirsevimab were supported by three clinical trials in over 3,000 infants. The efficacy of nirsevimab against medically attended RSV lower respiratory tract disease ranged from 70% to 75%, evaluated through 150 days after administration based on data from two of the supportive clinical trials. The most common adverse events in these studies were rash and injection site reactions.

The clinical trials supporting the FDA's approval of nirsevimab may not be large enough to detect rare adverse events, which may be seen only after hundreds of thousands of children are treated. In addition, the short duration of these studies may limit the ability to identify adverse events with delayed onset.

Health care providers play a vital role in helping the FDA effectively monitor postmarket safety. As such, the FDA is encouraging health care providers to report adverse events, even if they are not sure if nirsevimab caused the event. It also is important to report medication errors and near misses that may or may not result in an adverse event. Detailed information about the product, patient and the event is critical to enable the FDA to evaluate any potential risks associated with nirsevimab.

*The FDA's Office of Pediatric Therapeutics, Office of New Drug's Division of Pediatrics and Maternal Health and Division of Antivirals, Office of Surveillance and Epidemiology (drugs), and Office of Biostatistics and Pharmacovigilance (biologics) contributed to this article.*

## **Resources**

- [MedWatch Adverse Event Reporting Program](#)
- [Nirsevimab labeling](#)
- [AAP News story "AAP releases nirsevimab guidance, calls for continued access to palivizumab."](#)