Beyfortus® (nirsevimab-alip) 50 mg 100 mg Injection

Beyfortus® helps protect against respiratory syncytial virus (RSV) disease through direct administration to the infant[1]

Beyfortus is the **first and only long-acting antibody** indicated for the **prevention of RSV lower respiratory tract disease** in[1]:

- Neonates and infants born during or entering their first RSV season
- Children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season

IMPORTANT SAFETY INFORMATION

Contraindication

Beyfortus is contraindicated in infants and children with a history of serious hypersensitivity reactions, including anaphylaxis, to nirsevimab-alip or to any of the excipients.

Please see additional Important Safety Information throughout this brochure and accompanying full Prescribing Information.

Recommendations

ACOG guidelines state that clinicians should counsel patients regarding the monoclonal antibody, Beyfortus®, as another option for newborns if the maternal RSV vaccine is not received during pregnancy.[2]*

- When possible, discussions regarding Beyfortus should include information about whether it will be available to the baby after birth

Infants <34 weeks[2]

Infants born at less than 34 weeks should receive Beyfortus regardless of maternal vaccination status.

Infants at risk[2]

Infants born to mothers who received RSV vaccination ≥14 days before birth may receive Beyfortus based on clinical judgment.

CDC/ACIP recommends Beyfortus for infants born before the RSV season, as well as those born during the season when[3]:

- The mother did not receive the RSV maternal vaccine, or
- The mother's vaccination status is not known, or
- The window between maternal vaccination and birth was <14 days, or
- The healthcare provider determines the incremental benefit of Beyfortus is warranted because the infant is at increased risk, or when there are concerns about the adequacy of the maternal immune response or placental antibody transfer

*Patient preferences for maternal vs infant immunization against RSV should be considered when deciding to administer Beyfortus.

IMPORTANT SAFETY INFORMATION (cont'd)
Warnings and Precautions

- **Hypersensitivity Reactions Including Anaphylaxis:** Serious hypersensitivity reactions have been reported following Beyfortus administration. These reactions included urticaria, dyspnea, cyanosis, and/or hypotonia. Anaphylaxis has been observed with human immunoglobulin G1 (IgG1) monoclonal antibodies. If signs and symptoms of anaphylaxis or other clinically significant hypersensitivity reactions occur, initiate appropriate treatment.

Beyfortus® recommendations by CDC/ACIP and AAP[4,5]

First RSV season

Infants aged <8 months born during or entering their first RSV season are recommended to receive 1 dose of Beyfortus (50 mg for infants <5 kg and 100 mg for infants ≥5 kg).[4]

- Providers should target administration shortly before the start of the season for infants aged <8 months
- Beyfortus should be administered within 1 week of birth, which can be during the birth hospitalization or in the outpatient setting

Refer to the most current CDC immunization schedule for additional immunization considerations.

CDC/ACIP recommends that pregnant people should be aware that both maternal vaccination and immunization with Beyfortus are options when deciding how to help protect infants from RSV.[3]

- Passive immunization with Beyfortus given directly to newborns assures direct receipt of antibodies with no reliance on transplacental transfer

AAP, American Academy of Pediatrics; **ACIP**, Advisory Committee on Immunization Practices; **ACOG**, American College of Obstetricians and Gynecologists; **CDC**, Centers for Disease Control and Prevention.

IMPORTANT SAFETY INFORMATION (cont'd)
Warnings and Precautions (cont'd)

- **Use in Individuals with Clinically Significant Bleeding Disorders:** As with other IM injections, Beyfortus should be given with caution to infants and children with thrombocytopenia, any coagulation disorder or to individuals on anticoagulation therapy.

Most common adverse reactions with Beyfortus were rash (0.9%) and injection site reactions (0.3%).

Please see additional Important Safety Information throughout this brochure and accompanying full Prescribing Information.

Beyfortus® is the only long-acting antibody designed for RSV disease protection through 5 months[1]

Direct

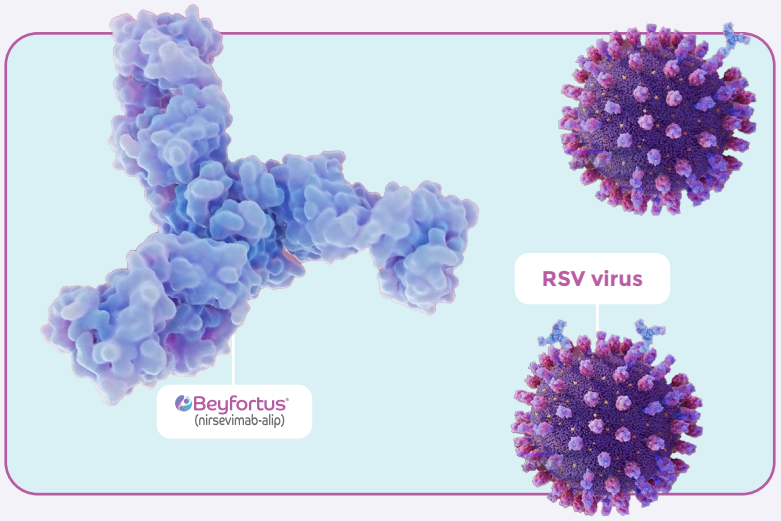
Antibody administration directly to newborns that does not rely on the infant's maturing immune system

Long-acting

- Long-acting antibody modified to extend its half-life
- RSV disease protection through 5 months—the typical RSV season—based on clinical data

Antibody

Monoclonal antibody (mAb) that provides passive immunity by inhibiting RSV F (fusion) protein to prevent viral entry into cells



IMPORTANT SAFETY INFORMATION

Contraindication

Beyfortus is contraindicated in infants and children with a history of serious hypersensitivity reactions, including anaphylaxis, to nirsevimab-alip or to any of the excipients.

Please see additional Important Safety Information throughout this brochure and accompanying full Prescribing Information.

Beyfortus® has proven strong and consistent efficacy against RSV disease[1]*

Primary endpoint: incidence of medically attended RSV-LRTI vs placebo through 150 days post 1 dose

Healthy term and late preterm infants ≥35 wGA (Trial 04)

⬇74.9% RRR

(95% CI: 50.6, 87.3; *P*<0.001)

Beyfortus: 1.2% (12/994) Placebo: 5.0% (25/496)

Healthy preterm infants ≥29 to <35 wGA (Trial 03)

⬇70.1% RRR

(95% CI: 52.3, 81.2; *P*<0.001)

Beyfortus: 2.6% (25/969) Placebo: 9.5% (46/484)

RSV disease protection that extends through 5 months based on clinical data[1]

CI, confidence interval; **IM**, intramuscular; **RSV-LRTI**, respiratory syncytial virus lower respiratory tract disease; **RRR**, relative risk reduction; **wGA**, weeks gestational age.

*Results of Trials 04 and 03 for infants entering their first RSV season. Trial 04 evaluated the efficacy of a single dose of Beyfortus (50 mg IM if <5 kg weight, 100 mg IM if ≥5 kg weight) vs placebo in 1,490 healthy term and preterm infants (≥35 wGA). Trial 03 evaluated the efficacy of a single 50 mg dose of Beyfortus vs placebo in 1,453 healthy preterm infants (≥29 to <35 wGA).

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions

- **Hypersensitivity Reactions Including Anaphylaxis:** Serious hypersensitivity reactions have been reported following Beyfortus administration. These reactions included urticaria, dyspnea, cyanosis, and/or hypotonia. Anaphylaxis has been observed with human immunoglobulin G1 (IgG1) monoclonal antibodies. If signs and symptoms of anaphylaxis or other clinically significant hypersensitivity reactions occur, initiate appropriate treatment.

Demonstrated consistent safety profile across multiple healthy infant cohorts[1,6-8]

Trial 04 and Trial 03 were pooled to evaluate the safety of Beyfortus® (N=2,570) compared with placebo (N=1,284).

- The Beyfortus group included 1,998 healthy term and late preterm infants (≥35 wGA) and 572 preterm infants (≥29 to <35 wGA)[1]
- Adverse reactions were reported in 1.2% of infants who received Beyfortus; most (97%) adverse reactions were mild to moderate in severity[1]

Most Common Adverse Reactions Reported at an Incidence Higher Than Placebo in the Safety Population (Trial 04 and Trial 03)[1]*

Adverse Reaction	Beyfortus N=2,570	Placebo N=1,284
Rash† (occurring within 14 days post dose)	0.9%	0.6%
Injection Site Reaction‡ (occurring within 7 days post dose)	0.3%	0.0%

*The Safety Population includes all infants who received the recommended dose of Beyfortus in Trials 04 and 03: Primary and Safety cohorts from Trial 04; infants who weighed <5 kg and who received the recommended dose of Beyfortus (single 50 mg IM dose) in Trial 03.
†Rash was defined by the following grouped preferred terms: rash, rash macular, rash maculopapular, rash papular.
‡Injection site reaction was defined by the following grouped preferred terms: injection site reaction, injection site pain, injection site induration, injection site edema, injection site swelling.

IMPORTANT SAFETY INFORMATION (cont'd)
Warnings and Precautions (cont'd)

- **Use in Individuals with Clinically Significant Bleeding Disorders:** As with other IM injections, Beyfortus should be given with caution to infants and children with thrombocytopenia, any coagulation disorder or to individuals on anticoagulation therapy.

Most common adverse reactions with Beyfortus were rash (0.9%) and injection site reactions (0.3%).

Administration timed to the RSV season[1]

Beyfortus® provides passive immunization that extends through 5 months, the typical length of the RSV season, regardless of birth month[1,9]

The ideal timing for Beyfortus dosing is just before or near the start of the first RSV season or from birth for infants born shortly before or during the RSV season[1]

Patients should consult with their pediatrician to determine the right time to immunize newborns born outside of the RSV season.

References: 1. Beyfortus (nirsevimab-alip). Prescribing Information. Sanofi. **2.** Maternal Respiratory Syncytial Virus Vaccination. American College of Obstetricians and Gynecologists. Published September 2023. Accessed November 13, 2023. https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2023/09/maternal-respiratory-syncytial-virus-vaccination **3.** Fleming-Dutra KE, Jones JM, Roper LE, et al. Use of the Pfizer respiratory syncytial virus vaccine during pregnancy for the prevention of respiratory syncytial virus–associated lower respiratory tract disease in infants: recommendations of the Advisory Committee on Immunization Practices. *MMWR Morb Mortal Wkly Rep*. 2023;72(41):1115-1122. **4.** 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(34):920-925. **5.** ACIP and AAP recommendations for nirsevimab. American Academy of Pediatrics. Published August 15, 2023. Accessed October 7, 2023. https://publications.aap.org/redbook/resources/25378/ACIP-and-AAP-Recommendations-for-Nirsevimab **6.** Domachowske J, Madhi SA, Simões EAF, et al. Safety of nirsevimab for RSV in infants with heart or lung disease or prematurity. *N Engl J Med*. 2022;386(9):892-894. **7.** Griffin MP, Yuan Y, Takas T, et al. Single-dose nirsevimab for prevention of RSV in preterm infants. *N Engl J Med*. 2020;383:415-425. **8.** Hammitt LL, Dagan R, Yuan Y, et al. Nirsevimab for prevention of RSV in healthy late-preterm and term infants. *N Engl J Med*. 2022;386:837-846. **9.** Obando-Pacheco P, Justicia-Grande AJ, Rivero-Calle I, et al. Respiratory syncytial virus seasonality: a global overview. *J Infect Dis*. 2018;217(9):1356-1364.

IMPORTANT SAFETY INFORMATION
Contraindication

Beyfortus is contraindicated in infants and children with a history of serious hypersensitivity reactions, including anaphylaxis, to nirsevimab-alip or to any of the excipients.

Please see additional Important Safety Information throughout this brochure and accompanying full Prescribing Information.

Beyfortus® (nirsevimab-alip) 50 mg 100 mg Injection

Fast-acting passive immunization to help prevent RSV disease that lasts through 5 months, a typical RSV season[1,9]

Beyfortus® helps prevent RSV lower respiratory tract disease in neonates and infants born during or entering their first RSV season[1]

- ✔ **The only long-acting antibody designed for RSV disease protection through 5 months[1]**
- ✔ **Available at little to no cost through the Vaccines for Children Program (VFC) and certain commercially insured programs**
- ✔ **Broad commercial coverage in place**

Counsel your patients on how Beyfortus® helps protect against RSV disease through direct administration to the infant.[1]
Visit Beyfortus.com to learn more.

IMPORTANT SAFETY INFORMATION

Contraindication

Beyfortus is contraindicated in infants and children with a history of serious hypersensitivity reactions, including anaphylaxis, to nirsevimab-alip or to any of the excipients.

Please see additional Important Safety Information throughout this brochure and accompanying full Prescribing Information.

sanofi

SANOFI
1 Discovery Drive
Swiftwater, PA 18370

MAT-US-2403100-v1.0-04/2024