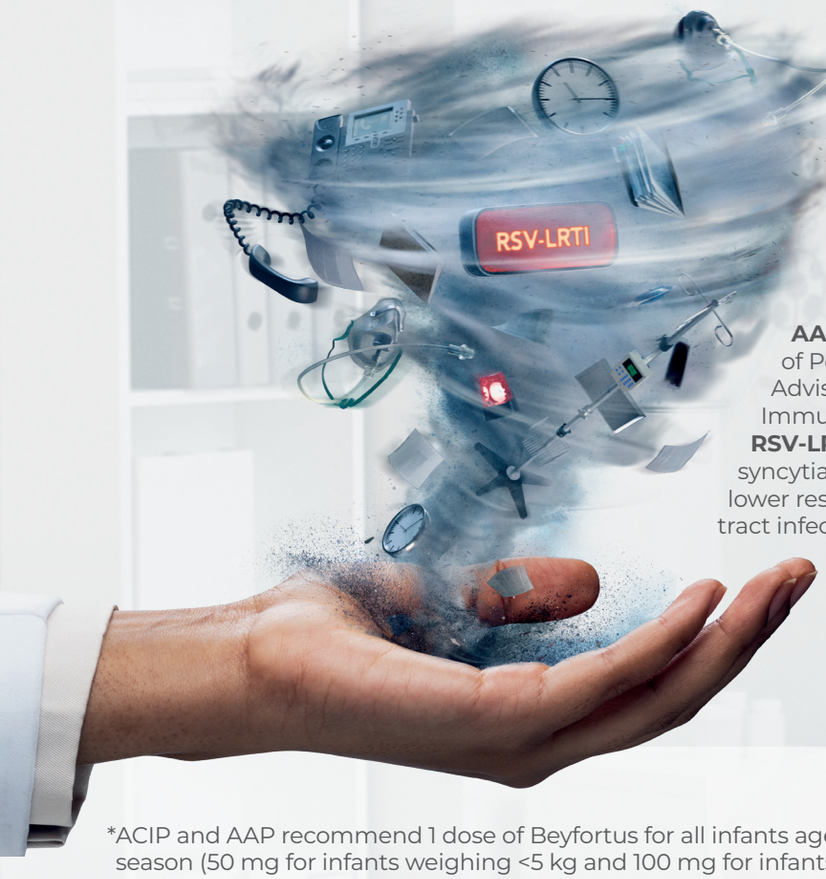
FAQs When Implementing Beyfortus®

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

ACIP and AAP recommended[1,2*]

Beyfortus is the **first and only long-acting antibody** indicated for the **prevention of RSV lower respiratory tract disease** in[3]:

- 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



AAP, American Academy of Pediatrics; **ACIP**, Advisory Committee on Immunization Practices; **RSV-LRTI**, respiratory syncytial virus lower respiratory tract infection.

*ACIP and AAP recommend 1 dose of Beyfortus for all infants aged <8 months born during or entering their first RSV season (50 mg for infants weighing <5 kg and 100 mg for infants weighing ≥5 kg). ACIP and AAP recommend 1 dose of Beyfortus (200 mg administered as 2 intramuscular injections [2 x 100 mg]) for children aged 8-19 months who are at increased risk of severe RSV disease and entering their second RSV season. Refer to the most current Centers for Disease Control and Prevention immunization schedule for additional immunization.[1,2]

INDICATION

Beyfortus is indicated for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease in:

- 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 and accompanying full Prescribing Information.

Using this guide

The Beyfortus® Implementation FAQ Guide was designed to provide you and your colleagues with the answers to commonly asked questions about Beyfortus.

While this information is relevant to anyone prescribing Beyfortus, this guide also includes questions commonly asked by those in a hospital setting while others are asked by those in a clinic setting.

KEY

Hospital-focused questions	Clinic-focused questions

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Please call **1-855-BEYFORTUS (1-855-239-3678)** if you have questions or need further support.

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.

General information about Beyfortus®

Q: Is Beyfortus a maternal immunization, vaccine, or monoclonal antibody?

Beyfortus is not a vaccine or maternal immunization.[3]
Beyfortus is an RSV F protein–directed fusion inhibitor monoclonal antibody indicated for the prevention of RSV lower respiratory tract disease, directly administered to infants as well as eligible children via intramuscular (IM) injection. Beyfortus does not require an immune response from the infant.

Q: What are the ACIP recommendations on the use of Beyfortus?

Beyfortus has been recommended by the ACIP as well as the AAP. The recommendations by both are the same[1,2]:

Infants aged <8 months

1 dose of Beyfortus for all infants aged <8 months born during or entering their first RSV season (50 mg for infants weighing <5 kg and 100 mg for infants weighing ≥5 kg).

Infants and children aged 8-19 months

1 dose of Beyfortus (200 mg administered as 2 intramuscular injections [2 x 100 mg]) for children aged 8-19 months who are at increased risk of severe RSV disease and entering their second RSV season.

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

Q: Can Beyfortus be co-administered with pediatric vaccines?

Beyfortus can be administered concomitantly with other childhood vaccines.[3]

- There is limited experience of Beyfortus coadministration with vaccines. In clinical trials, when Beyfortus was given with routine childhood vaccines, the safety and reactogenicity profile of the coadministered regimen was similar to the childhood vaccines given alone
- Beyfortus should not be mixed with any vaccine in the same syringe or vial. When administered concomitantly with injectable vaccines, they should be given with separate syringes and at different injection sites

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 and accompanying full Prescribing Information.

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

General information about Beyfortus®

Q: What are the Contraindications and Warnings and Precautions for Beyfortus?

Contraindication

Beyfortus is contraindicated in individuals with a history of serious hypersensitivity reactions, including anaphylaxis, to nirsevimab-alip or to any of the excipients.[3]

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.[3]

Use in Individuals with Clinically Significant Bleeding Disorders

As with any other IM injections, Beyfortus should be given with caution to individuals with thrombocytopenia, any coagulation disorder or to individuals on anticoagulation therapy.[3]

Q: What are the most common reactions of Beyfortus?

In clinical studies, safety results found that the majority of adverse reactions were mild to moderate in severity. The most common adverse reactions were rash (0.9%) and injection site reactions (0.3%).[3]

You may report side effects to the FDA at 1-800-FDA-1088.

Q: Who should not receive Beyfortus?

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.[3]

Q: What are the ingredients in Beyfortus?

- Active ingredient: nirsevimab-alip[3]
- Inactive ingredients: arginine hydrochloride, histidine, L-histidine hydrochloride monohydrate, polysorbate 80, sucrose, and water for injection[3]

IM, intramuscular.

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 and accompanying full Prescribing Information.

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

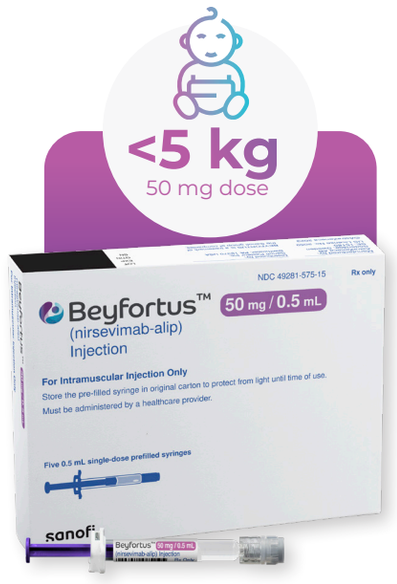
General information about Beyfortus®

Q: Is Beyfortus latex- or preservative-free?

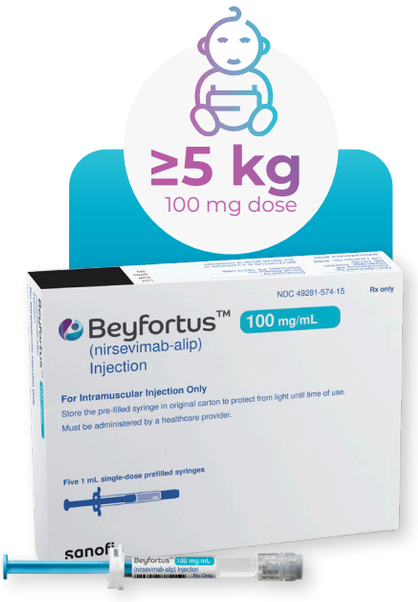
Yes. Beyfortus injection is a sterile, latex-free, preservative-free, clear to opalescent, colorless to yellow solution for intramuscular injection.[3,4]

Q: What is the size of Beyfortus packaging (for storage purposes)?

Beyfortus is supplied as follows[3,5]:



Carton of 5 X 50 mg (0.5 mL)
140 x 108 mm (5.5" x 4.25")
Syringe is maximum of ~100 mm



Carton of 5 x 100 mg (1 mL)
140 x 108 mm (5.5" x 4.25")
Syringe is maximum of ~120 mm

Please see next page or accompanying full Prescribing Information for details on dosing and administration.

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.

Please see additional Important Safety Information and accompanying full Prescribing Information.

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

Choosing the appropriate dose for your patient

Q: For infants in their first RSV season, how do I determine whether to give 50 mg vs the 100 mg injection?

The recommended dosage of Beyfortus® for neonates and infants born before or during their first RSV season is **based on body weight and is administered as a single IM injection**[3]:

Recommended Dosage of Beyfortus for Their First RSV Season[3]

Body Weight at the Time of Dosing	Recommended Dosage
<5 kg	50 mg (0.5 mL) by IM injection
≥5 kg	100 mg (1.0 mL) by IM injection

For children undergoing cardiac surgery with cardiopulmonary bypass (in the first or second season), an additional dose of Beyfortus is recommended as soon as the child is stable after surgery; please consult the accompanying full Prescribing Information or next page for complete information on dosing in these circumstances.[3]

Q: For infants in their second RSV season, how do I determine Beyfortus dosing?

Second season: for children up to 24 months of age, regardless of body weight, who remain at increased risk for severe RSV, the recommended dosage of Beyfortus is **a single 200 mg dose administered as 2 IM injections (2 x 100 mg)**.[3]

Q: Who is considered "vulnerable through their second RSV season" when considering second season dosing with Beyfortus?

According to ACIP and AAP second RSV season guidelines, infants and children aged 8-19 months with increased risk for severe disease who are recommended to receive Beyfortus when entering their second RSV season include[2]:

- **Children with chronic lung disease of prematurity** who required medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) any time during the 6-month period before the start of the second RSV season
- **Severely immunocompromised children**
- **Children with cystic fibrosis** who have either manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable) or weight-for-length <10th percentile
- **American Indian or Alaska Native children**

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 and accompanying full Prescribing Information.

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

Choosing the appropriate dose for your patient

Q: What are the dosing guidelines for infants who have undergone cardiac surgery with cardiopulmonary bypass?

For these children, an additional dose may be necessary as soon as the infant is stable after surgery.[3]

First RSV Season	Second RSV Season
• If surgery is within 90 days after receiving Beyfortus®, the additional dose should be based on body weight at the time of the additional dose • If more than 90 days have elapsed since receiving Beyfortus, the additional dose should be 50 mg, regardless of body weight	• If surgery is within 90 days after receiving Beyfortus, the additional dose should be 200 mg, regardless of body weight • If more than 90 days have elapsed since receiving Beyfortus, the additional dose should be 100 mg, regardless of body weight

Q: Should Beyfortus be administered if the patient's mother was immunized with an RSV vaccine within 2 weeks of birth?

Per CDC guidelines, one dose of Beyfortus is recommended for infants younger than 8 months of age who were born during or are entering their first RSV season (typically fall through spring for most of the continental US) if the infant was born within 14 days of maternal RSV vaccination.[1,6]

As a reminder, the ACIP recommendation for the RSV maternal immunization is seasonal.[5]

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

Q: In what other instances is Beyfortus recommended when considering the mother's RSV vaccination history?

Beyfortus is recommended for infants aged <8 months born during or entering their first RSV season[6,7]*:

- Whose mother did not receive the RSV maternal immunization with their recent pregnancy
- Whose mother's receipt of the RSV maternal immunization is unknown
- Who were born <14 days after maternal immunization
- Beyfortus may be considered for infants whose mother received the RSV maternal immunization, and, based on the clinical judgment of the healthcare provider, the potential incremental benefit of administration is warranted
- Current recommendations for 2024-2025 are for a single lifetime dose of the RSV maternal vaccine during pregnancy and that Beyfortus should be used for infants born to mothers who received the RSV vaccine during a previous pregnancy

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

*Beyfortus is not needed for most infants aged <8 months whose mother received the RSV maternal immunization ≥14 days before birth.

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 and accompanying full Prescribing Information.

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

Optimal timing for Beyfortus® immunization

Q: When does RSV season start and end in the US?

- **The typical RSV season lasts for 5 months**, although the timing of the onset, peak, and decline of RSV activity might vary geographically[6]
- **Based on ACIP regional administration guidelines, providers can adjust administration schedules based on local epidemiology**[6]
  - RSV seasonality in tropical climates (including Southern Florida, Guam, Hawaii, Puerto Rico, US-affiliated Pacific Islands, and US Virgin Islands) might differ
  - In Alaska, RSV seasonality is less predictable, and the duration of RSV activity is often longer than the national average duration
- **Providers in these jurisdictions should consult state, local, or territorial guidance on timing of Beyfortus administration**[6]

Q: When do I start giving Beyfortus to patients?

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**. Per the approved label, you can administer Beyfortus throughout the RSV season.[3]

For information on when the season begins in your area, check with your local AAP chapter, state health department, or other local expert for guidance.

Q: How do I know when to dose an infant based on my setting of care?

ACIP guidelines recommend Beyfortus for all infants aged <8 months born during or entering their first RSV season.[1]

For hospitals:

- If the infant is born during the RSV season, administer Beyfortus in the hospital at birth, prior to discharge

For clinics:

- If not given prior to discharge, administer Beyfortus at the well-baby visit, within 1 week of discharge. If the Infant is born outside of the RSV season, Beyfortus may be administered at the regularly scheduled 2-, 4-, or 6- month well-baby visit

Please see page 6 or accompanying full Prescribing Information for details on dosing and administration.

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.

Please see additional Important Safety Information and accompanying full Prescribing Information.

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

Optimal timing for Beyfortus® immunization

Q: When do I stop giving Beyfortus to patients?

Per the approved label, **you can administer Beyfortus throughout the RSV season**, although you should note that timing of the season can vary based on geographic region.[3]

For information on when the season ends in your area, check with your local AAP chapter, state health department, or other local expert for guidance.

Q: If an infant is born outside the RSV season, when should that infant receive Beyfortus?

Using a hypothetical infant who is born 4 months before the start of the RSV season, it is recommended to administer Beyfortus in the clinical setting at the infant's 4-month well-baby visit at the start of the RSV season. Epidemiology research will further define when local RSV seasons start. See indication and full dosing information.[3]

Q: If an infant is 7 months old, how many doses of Beyfortus does the infant get?

For a hypothetical infant who is 7 months old and in their first RSV season, the recommended dosage of Beyfortus is a single IM injection of 50 mg or 100 mg based on body weight.[3]

For children undergoing cardiac surgery with cardiopulmonary bypass, an additional dose of Beyfortus is recommended as soon as the child is stable after surgery; please consult the full Prescribing Information for complete information on dosing in these circumstances.[3]

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 and accompanying full Prescribing Information.

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

Beyfortus® use in a hospital vs a clinic setting

Q: How do I ensure infants are dosed in the hospital at birth, prior to discharge?

For hospitals:

- Work with your hospital administration team to ensure that Beyfortus is included in existing newborn protocols in the hospital, particularly for Vaccines for Children (VFC) Program–eligible and privately insured patients
- Enrollment may help to ensure health equity across patient populations
- Both hospitals and clinics can enroll and activate the VFC Program

For clinics:

- Work with the hospital(s) in your area to understand the administration protocols related to Beyfortus for newborns
- This can aid in understanding whether you need to prepare to dose at the first outpatient (3-5 day) well-baby visit for infants born during the RSV season or if this will have already been covered in the hospital

Q: How do I ensure infants born outside a typical RSV season are dosed in my clinic at the start of RSV season?

Pediatricians can flag all newborn patients to their practice born before their first RSV season for Beyfortus administration in the fall.

The pediatrician can begin screening infants for receipt of Beyfortus beginning a month before the local RSV season starts and administer if needed.

For infants needing immunization in their second season, pediatricians should establish criteria for whom they anticipate dosing. These infants should be tracked and reminders should be sent to their parents to ensure these infants receive care where needed.

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 and accompanying full Prescribing Information.

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

Beyfortus® use in a hospital vs a clinic setting

Q: Will Beyfortus be covered if I use it outside of a typical RSV season?

As of now, we are not aware of any payer policies that define the season by a specific timeline. We encourage you to confirm coverage status with your payers directly.

Q: How do I ensure staff is trained on weight-based dosing at time of administration for infants dosed during their first season?

Sanofi has resources available to help train staff about dosing with Beyfortus, including dosing shelf talkers and a dosing and administration wall poster, which clarify the different color packaging for each dose.

Please reach out to your Sanofi representative or call **1-855-BEYFORTUS (1-855-239-3678)** if you need further support.

Q: Where can I find information to share with parents?

Speak with your Sanofi representative or call customer service at **1-855-BEYFORTUS (1-855-239-3678)**. You can also access materials for your patients at **Beyfortus.com** under "Parent Support".

References

1. 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. **2.** AAP Recommendations for the Prevention of RSV Disease in Infants and Children. American Academy of Pediatrics. Published February 21, 2024. Accessed May 20, 2024. https://publications.aap.org/redbook/resources/25379/AAP-Recommendations-for-the-Prevention-of-RSV **3.** Beyfortus (nirsevimab-alip). Prescribing Information. Sanofi. **4.** Data on file, October 2023. **5.** Data on file, May 2024. **6.** 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. **7.** Yonts AB, Gaviria-Agudelo C, Kimberlin DW, Paulsen GC, O'Leary ST. June 2024 ACIP meeting update: influenza, COVID-19, RSV and other vaccines. *Pediatrics*. 2024;154(4):e2024068310.

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.

Please see additional Important Safety Information and accompanying full Prescribing Information.

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

Power to help prevent RSV disease

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

The **first and only long-acting antibody** indicated for the **prevention of RSV lower respiratory tract disease** in term and preterm infants[3]

Proven strong and consistent efficacy against MA RSV-LRTI[3]*

- In healthy term and late preterm infants, **74.9%** (95% CI: 50.6, 87.3; *P*<0.001) **RRR** of medically attended (MA) RSV-LRTI through 150 days post 1 dose – primary endpoint, Trial 04 (Beyfortus®: 1.2% [12/994] placebo: 5.0% [25/496])
- In healthy preterm infants, **70.1%** (95% CI: 52.3, 81.2; *P*<0.001) **RRR** of MA RSV-LRTI through 150 days post 1 dose – primary endpoint, Trial 03 (Beyfortus: 2.6% [25/969] placebo: 9.5% [46/484])

Demonstrated safety profile vs placebo (Trials 04 and 03) and vs palivizumab (Trial 05)[3†‡]

- The most common adverse events in Trial 04 and Trial 03 were rash (0.9%) and injection site reactions (0.3%)
- Adverse reactions reported among Trial 05 infants and children <24 months were similar to Trials 04 and 03

RSV disease protection that extends through 5 months based on clinical data[3]

Visit Beyfortus.com to learn more about protection against RSV disease.

Call 1-855-BEYFORTUS (1-855-239-3678) for more information and support.

CI, confidence interval; **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).

†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 less than 5 kg and who received the recommended dose of Beyfortus (single 50 mg IM dose) in Trial 03.

‡Trial 05 was a Phase 2/3, randomized, double-blind, palivizumab-controlled study evaluating the safety of Beyfortus in infants with chronic lung disease (CLD) or congenital heart disease (CHD) and preterm infants (<35 wGA) entering their first RSV season, as well as children with CLD or CHD up to 24 months of age continuing in the trial for a 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.

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.
- **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 accompanying full Prescribing Information.

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MAT-US-2403478-v2.0-09/2024