Over 13 million infants received Beyfortus® worldwide with over **half a million in Canada**[1*]

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REAL-WORLD DATA

EXPLORE BEYFORTUS® DATA FROM THE HARMONIE TRIAL

Less hospitalizations due to RSV seen with Beyfortus® vs. no intervention in an open-label trial under real-world conditions

83.2% RRR in preventing RSV LRTI hospitalizations in term and preterm infants seen with Beyfortus® (11/4,037) vs. the no intervention group (60/4,021)[2†] (95% CI: 67.8, 92.0; p<0.0001)



Beyfortus* (nirsevimab injection) is indicated for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease in:[2]

- Neonates and infants during their first RSV season.
- Children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season, which may include but is not limited to children with: chronic lung disease of prematurity (CLD), hemodynamically significant congenital heart disease (CHD), immunocompromised states, Down syndrome, cystic fibrosis, neuromuscular disease, and congenital airway anomalies.

Content enhanced by AI.

CI=confidence interval; GA=gestational age; IM=intramuscular; LRTI=lower respiratory tract infection; RRR=relative risk reduction.
* Clinical significance unknown.
† HARMONIE: Phase 3b, randomized, open-label, multicentre trial in 8,034 healthy term and preterm infants (GA ≥29 weeks) entering their first RSV season who received a single IM dose of Beyfortus® (50 mg if <5 kg weight or 100 mg if ≥5 kg at time of administration) (n=4,037) or no intervention (n=4,021) for the prevention of RSV LRTI hospitalization. The trial was conducted under real-world conditions. Efficacy was estimated accounting for the follow-up time to emulate real-world conditions. Primary endpoint was overall incidence of RSV LRTI hospitalization through RSV season caused by confirmed RSV infection.

Beyfortus® (nirsevimab)

Administering Beyfortus® for neonates and infants entering their first RSV season[2]

A **single administration** based on infant's weight at the time of receiving Beyfortus®

<5 kg
1 x 50 mg dose

Dosing in infants with a body weight of 1.0 kg to <1.6 kg is based on extrapolation.

≥5 kg
1 x 100 mg dose



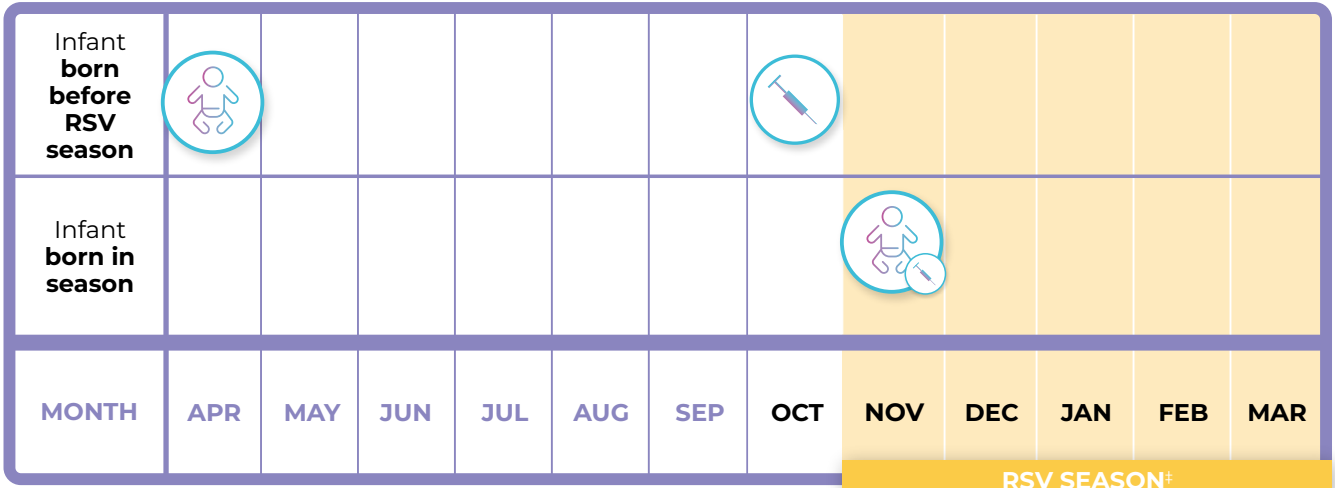
Available as a ready-to-use pre-filled syringe

IM injection, preferably in the anterolateral aspect of the thigh*

When applicable, Beyfortus® can be **administered concomitantly** with childhood vaccines†

* The gluteal muscle should not be used routinely as an injection site because of the risk of damage to the sciatic nerve.
† 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. Consult the Product Monograph for complete information regarding drug interactions.

Beyfortus® should be administered prior to the RSV season or from birth for infants born during the RSV season[2]



Illustrative example only.§

Infant birth month

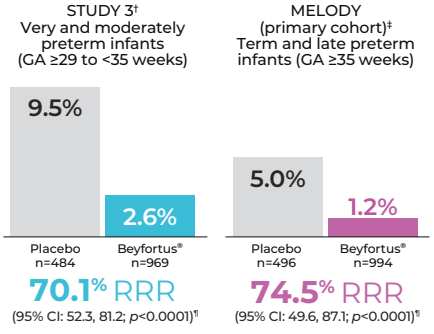
Immunization with Beyfortus®

Consult the Product Monograph for complete dosing and administration recommendations

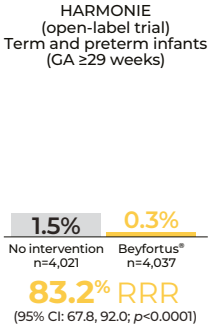
‡ Shaded area indicates a typical RSV season in a temperate northern hemisphere climate. The RSV season varies by region.[3]
§ Chart represents examples only and not mandatory/recommended specific timings.

Efficacy data
In term and preterm infants entering their first RSV season[2]

Incidence of MA RSV LRTI (including hospitalizations) caused by RT-PCT-confirmed RSV, characterized predominantly as bronchiolitis or pneumonia, through 150 days post dose*



Incidence of RSV LRTI hospitalization through the RSV season in term and preterm infants caused by confirmed RSV infection in an open-label trial under real-world conditions§



Incidence of MA RSV LRTI requiring hospitalization through 150 days post injection in the MELODY trial (secondary endpoint; all subjects)

MELODY continued to enroll infants following the primary analysis, and overall, 3,012 infants (all subjects) were randomized to receive Beyfortus® (n=2,009) or placebo (n=1,003) following the primary analysis

- **76.8% RRR** in preventing MA RSV LRTI **requiring hospitalization** through to Day 150 seen with Beyfortus® (9/2,009; IR: 0.4%) vs. placebo (20/1,003; IR: 2.0%) (95% CI: 49.4, 89.4)

Adapted from Product Monograph.

IR=incidence rate; MA=medically attended; RT-PCR=reverse transcription polymerase chain reaction.

* Signs of LRTI defined as having one of the following findings at physical examination indicating lower respiratory tract involvement (e.g., rhonchi, rales, crackles, or wheeze) and ≥1 sign of clinical severity (increased respiratory rate, hypoxemia, acute hypoxic or ventilatory failure, new-onset apnea, nasal flaring, retractions, grunting, or dehydration due to respiratory distress). RSV hospitalization defined as hospitalization for LRTI with a positive RSV test or worsening of respiratory status and positive RSV test in an already hospitalized patient.

† Study 3: Phase 2b, randomized, double-blind, placebo-controlled, Phase IIb multicentre trial in 1,453 very and moderately preterm infants (GA ≥29 to <35 weeks) entering their first RSV season. Infants were randomized 2:1 to receive a fixed single IM dose of Beyfortus® 50 mg (n=969) or placebo (n=484). 50 mg is not a recommended dose for infants with body weight ≥5 kg. The recommended dose for infants with body weight ≥5 kg is a single IM dose of 100 mg.

‡ MELODY: Phase 3, randomized, double-blind, placebo-controlled, multicentre trial in term and late preterm infants (GA ≥35 weeks) entering their first RSV season (primary cohort, N=1,490). MELODY continued to enrol infants following primary analysis with 3,012 term and late preterm infants enrolled overall (all subjects). Infants were randomized 2:1 to receive a single IM dose of Beyfortus® (50 mg if <5 kg weight or 100 mg if ≥5 kg at time of administration) (n=994 and n=2,009) or placebo (n=496 and n=1,003) for the primary cohort and all subjects, respectively. Primary endpoint (MELODY [primary cohort]) was incidence of MA RSV LRTI (inclusive of hospitalization) caused by RT-PCR-confirmed RSV characterized predominantly as bronchiolitis or pneumonia through 150 days post dose.

¶ RRR and 95% CI were calculated using modified Poisson regression with robust variance including stratification factors (hemisphere and age at randomization).

§ HARMONIE: Phase 3b, randomized, open-label, multicentre trial in 8,034 healthy term and preterm infants (GA ≥29 weeks) entering their first RSV season who received a single IM dose of Beyfortus® (50 mg if <5 kg weight or 100 mg if ≥5 kg at time of administration) (n=4,037) or no intervention (n=4,021) for the prevention of RSV LRTI hospitalization. The trial was conducted under real-world conditions. Efficacy was estimated accounting for the follow-up time to emulate real-world conditions. Primary endpoint was overall incidence of RSV LRTI hospitalization through RSV season caused by confirmed RSV infection.

The content in this box is based on a matched observational analysis with non-randomized treatment assignment in France. Outcomes represent observed associations and should be interpreted cautiously, as they are not from a randomized controlled trial or included in the Product Monograph.

Real-World Evidence

Effectiveness data seen with Beyfortus® vs. maternal vaccination with RSVpreF in infants[4||]



Adapted from Jabagi, et al.

Key study limitations: As a non-randomized observational study, residual and unmeasured confounding cannot be excluded. Findings reflect one RSV season in mainland France, with limited representation of infants born earlier in the season.

End of Real-World Evidence

HR=hazard ratio; PICU=pediatric intensive care unit; RSVpreF=respiratory syncytial virus prefusion protein vaccine.

|| A population cohort study using the French National Health Data System. Study population consisted of 42,560 infants born between Sept. 1 and Dec. 31, 2024, who were immunized either through maternal vaccination with RSVpreF or with Beyfortus®. Each infant born to a mother vaccinated with the RSVpreF vaccine was matched 1:1 to an infant who received Beyfortus® by maternity discharge date, sex, gestational age and region, using random sampling without replacement. Follow-up ended at the time of RSV hospitalization or death or on February 28, 2025.

Includes the administration of supplemental oxygen, not ventilator or respiratory support.

Beyfortus® was generally well tolerated in clinical trials[2]

Rash was the most frequently reported adverse reaction (Beyfortus® 0.7%; placebo 0.3%) occurring within 14 days post dose

Pyrexia (Beyfortus® 0.5%) and injection site reactions (Beyfortus® 0.3%) occurred within 7 days post dose

STUDY 3/MELODY: pooled data in term and preterm infants (GA ≥29 weeks)

Safety profile for Beyfortus® was generally comparable to placebo

Overall rates of AEs, irrespective of causality, were comparable between Beyfortus® and placebo (84.0% and 82.6%) with the majority reported as mild or moderate in severity.

Most commonly reported AEs (>10% of subjects) for Beyfortus® vs. placebo were:
- upper respiratory tract infection (31.8% vs. 29.9%)
- nasopharyngitis (19.0% vs. 21.0%)
- pyrexia (11.8% vs. 10.3%)

Rates of SAEs, irrespective of causality, were comparable between Beyfortus® and placebo (7.6% and 10.5%); no SAEs were determined to be related to Beyfortus®.

Most commonly reported SAEs (≥0.5% of subjects) for Beyfortus® vs. placebo were:
- bronchiolitis (1.3% vs. 2.6%)
- pneumonia (0.7% vs. 0.9%)
- gastroenteritis (0.6% vs. 0.4%)
- LRTI (0.6% vs. 0.8%)
- bronchitis (0.5% vs. 1.0%)
- urinary tract infection (0.3% vs. 0.5%)
- RSV bronchiolitis (0.2% vs. 0.9%)
- inguinal hernia (<0.1% vs. 0.5%)

AE=adverse event; SAE=serious adverse event.

MEDLEY: infants at higher risk for severe RSV disease entering their first RSV season*

Safety profile of Beyfortus® (n=614) was comparable to palivizumab (n=304) and consistent with that seen in term and preterm infants ≥29 weeks GA (Study 3/MELODY)*†

Clinical use:

Safety and efficacy in children aged >24 months or in infants weighing <1.6 kg have not been established. Dosing in infants weighing 1.0 kg to <1.6 kg is based on extrapolation. Efficacy in infants who remain vulnerable to severe RSV disease during their first or second RSV season has not been directly established and is based on extrapolation of exposure only.

There is limited information available in extremely preterm infants (GA <29 weeks) <8 weeks of age, and no clinical data are available in infants with a postmenstrual age (GA at birth plus chronological age) of 32 weeks. Limited data are available in infants with Down syndrome (n=13), cystic fibrosis (n=5), congenital airway anomalies (n=9), and neuromuscular disease (n=0; not evaluated in clinical trials).

Not indicated in the geriatric population (≥65 years of age).

Relevant warnings and precautions:

- Administer with caution to individuals with thrombocytopenia, any coagulation disorder or to those on anticoagulation therapy.
- Use in individuals with protein-losing conditions: increased clearance of nirsevimab may reduce the level of protection.
- Potential for serious hypersensitivity reactions, including anaphylaxis. If signs and symptoms of anaphylaxis or other clinically significant hypersensitivity reaction occur, immediately discontinue and initiate appropriate medicinal products and/or supportive therapy.
- Pregnant and nursing women: not indicated for adults.

For more information:

Consult the Product Monograph at https://www.sanofi.com/assets/countries/canada/docs/products/vaccines/beyfortus-en.pdf for important information relating to adverse events, drug interactions, and dosing, which have not been discussed in this piece. The Product Monograph is also available by calling 1-800-265-7927.

* Safety was evaluated in 918 infants at higher risk of severe RSV disease, including 196 extremely preterm infants (GA <29 weeks) and 306 infants with CLD of prematurity or hemodynamically significant CHD entering their first RSV season, who received Beyfortus® (n=614) or palivizumab (n=304).

† There are limited data available in extremely preterm infants (GA <29 weeks) <8 weeks of age. No clinical data available in infants with a postmenstrual age (GA at birth plus chronological age) of 32 weeks. Limited data are available in infants with Down syndrome (n=13), cystic fibrosis (n=5), congenital airway anomalies (n=9), and neuromuscular disease (n=0; not evaluated in clinical trials).

Consider Beyfortus® [2]
(nirsevimab)



Less hospitalizations due to RSV with Beyfortus® in the HARMONIE trial
Beyfortus® reduced the relative risk of RSV LRTI hospitalizations in term and preterm infants vs. no intervention in an open-label trial under real-world conditions.[2]



Assessed in **four clinical studies**, in **>12,100 infants** across **31 countries**[1,2]*†

Designed to **evaluate** the following **infant populations**:[2]

- Healthy infants born preterm (Study 3; N=1,453)
- Healthy infants born late preterm and term (MELODY; N=1,490 primary cohort)
- Individuals at high risk for severe RSV disease (MEDLEY; N=925)
- Healthy infants (term and preterm) under real-world conditions (HARMONIE; N=8,057)

Content enhanced by AI.

* Beyfortus® was assessed in four clinical studies: Study 3 (phase 2b, randomized, double-blind, placebo-controlled study in healthy preterm infants); MELODY (phase 3, randomized, double-blind, placebo-controlled study in term and late preterm infants); MEDLEY (phase 2/3, randomized, double-blind, palivizumab-controlled study in individuals at higher risk for severe RSV disease including preterm infants, infants with CLD of prematurity or hemodynamically significant CHD entering their first RSV season, and children at higher risk including those with CLD or CHD in their second RSV season; and HARMONIE (phase 3b, randomized, open-label study conducted under real-world conditions in healthy term and preterm infants (GA ≥29 weeks).[2]

† Clinical significance has not been established.

References: 1. Data on file, Sanofi Vaccines Canada Ltd., September 16, 2026. **2.** Beyfortus® Product Monograph, Sanofi Vaccines Canada Ltd., May 7, 2026. **3.** Obando-Pacheco P, et al. Respiratory syncytial virus seasonality: a global overview. *J Infect Dis* 2018;217:1356–64. **4.** Jabagi MJ, et al. Nirsevimab vs RSVpreF vaccine for respiratory syncytial virus–related hospitalization in newborns *JAMA* 2026;335(9):787–98.

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Sanofi & AstraZeneca are collaborating on the development and commercialization of Beyfortus®.
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