sanofi

RSV and

Beyfortus® ▼
(nirsevimab)

pocket guide

This material is intended for healthcare professionals in Ireland only – it should not be given or shown to parents, caregivers, or the general public.

Beyfortus® is indicated for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease in:[1]
i. Neonates and infants during their first RSV season
ii. Children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season
Beyfortus® should be used in accordance with official recommendations.[1]

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

Adverse events should be reported. Reporting forms and information can be found at www.hpra.ie; email: medsafety@hpra.ie. Adverse events should also be reported to Sanofi Ireland Ltd. Tel: 01 403 5600. Alternatively, send via email to IEPharmacovigilance@sanofi.com.

Prescribing Information can be found on the back cover.

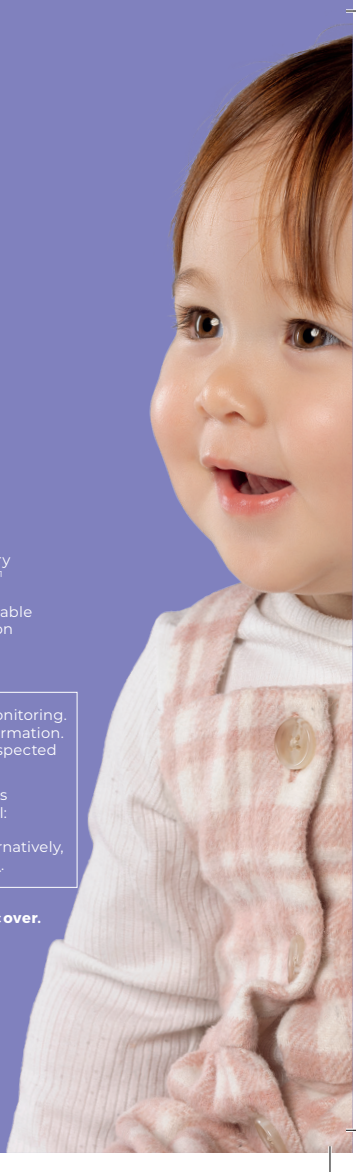
This item was funded and developed by Sanofi.

RSV, respiratory syncytial virus.

References

1. Beyfortus® IE Summary of Product Characteristics (SmPC). September 2024.

MAT-IE-2400226 (v2.0) September 2024



National Immunisation Advisory Committee (NIAC) recommend immunisation against RSV lower respiratory tract disease (LRTD) for infants born during the RSV season with nirsevimab.[1]

Beyfortus®: key facts

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Beyfortus®...

offers protection for: at least 5 months.*[2]

was studied in: almost 4,000 infants, including those born healthy, full-term, pre-term, and with underlying health conditions.[2–5]

* Based on clinical and pharmacokinetic data.[2]
** The gluteal muscle should not be used routinely as an injection site because of the risk of damage to the sciatic nerve. If two injections are required, different injection sites should be used.[2]
† For full dosing information, including information for individuals undergoing cardiac surgery with cardiopulmonary bypass, consult the Summary of Product Characteristics or see the prescribing information attached.
‡ Beyfortus® is available as a single dose of either 50 mg nirsevimab in 0.5 mL (100 mg/mL) or 100 mg nirsevimab in 1 mL (100 mg/mL).[2]

LRTD, lower respiratory tract disease; **NIAC,** National Immunisation Advisory Committee; **RSV,** respiratory syncytial virus.

is given as: a single intramuscular injection **only**, preferably in the anterolateral aspect of the thigh.**,[2] The recommended dose is a single dose of 50 mg for infants with bodyweight <5 kg and a single dose of 100 mg for infants with body weight ≥5 kg.[2] For children up to 24 months of age who remain vulnerable to severe RSV disease through their second season, the recommended dose is a single dose of 200 mg given as 2 injections (2 x 100 mg).†,[2]

comes in a pre-filled syringe, containing: the active substance, nirsevimab, and the excipients L-histidine, L-histidine hydrochloride, L-arginine hydrochloride, sucrose, polysorbate 80 and water for injections.†,[2]

should be stored: in a refrigerator (2°C–8°C).[2] Do not freeze, shake or expose to direct heat.[2] Keep in outer carton to protect from light.[2] Beyfortus® may be kept at room temperature (20°C–25°C) when protected from light, for a maximum of 8 hours. After this time, the syringe must be discarded.[2] Beyfortus® has a shelf-life of 3 years.[2]

Safety information

The most frequent adverse reaction was rash (0.7%), occurring within 14 days post dose.[2] The majority of cases were mild to moderate in intensity.[2] Additionally, pyrexia and injection site reactions were reported at a rate of 0.5% and 0.3% within 7 days post dose, respectively.[2] Injection site reactions were non-serious.[2] **Hypersensitivity with not known frequency has also been observed. [2]**

Serious hypersensitivity reactions have been reported following Beyfortus administration.[2] Anaphylaxis has been observed with human immunoglobulin G1 (IgG1) monoclonal antibodies. If signs and symptoms of anaphylaxis or other clinically significant hypersensitivity reaction occur, immediately discontinue administration and initiate appropriate medicinal products and/or supportive therapy.[2]

For full adverse reaction information, please refer to the Beyfortus® (nirsevimab) Summary of Product Characteristics.

1. National Immunisation Advisory Committee (NIAC). Recommendations For The Passive Immunisation Of Infants Against Respiratory Syncytial Virus (RSV) During The 2024/2025 Season. Available at: https://www.nitag-resource.org/sites/default/files/2024-07/2024.04.16_NIAC_Recommendations_re._Passive_immunisation_of_.pdf Accessed: August 2024. 2. Beyfortus® IE Summary of Product Characteristics (SmPC). September 2024. 3. Griffin MP et al. N Engl J Med 2020; 383(5): 415–425. 4. Hammitt LL et al. N Engl J Med 2022; 386(9): 837–846. 5. Domachowske J et al. N Engl J Med 2022; 386(9): 892–894.

Parent FAQs:

"What's RSV disease? Is it serious?"

- For most babies, an RSV infection is a lot like a common cold,[1] but it sometimes leads to **lung infections** that can make it hard for them to breathe[1,2]
- RSV disease is a **leading cause of hospitalisation worldwide** in babies under a year old*[3,4]
- **Any baby is at risk** – it's **difficult to predict** which babies will develop infections requiring medical attention or even hospitalisation[4–7]
- **No treatments exist** for RSV except for the management of symptoms, which may include oxygen therapy or intravenous fluids for those who develop **bronchiolitis**[1,8]

* Based on US and French data.[3,4] US data from a systematic literature review and meta-analysis of studies published between 2000 and 2020 (comprised of data collected between 1989 and 2016) describing RSV-associated hospitalisation rates in US infants <1 year of age.[3] Among an analysis of 25 published studies including data collected from 1989 to 2016, which met inclusion criteria, the mean annual RSV-associated hospitalisation rate was 20 per 1,000 (2.0%) infants <1 year (95% CI: 17.3–22.6).[3] French data from a retrospective analysis of RSV-associated hospitalisation data from the French Hospital database (PMSI-MCO) which covers the entire French population from the years 2010 through 2018. The study included data from children up to 5 years of age (median n=45,988), of whom 69% (median n=31,570) were aged <1 year and 31% (median n=14,418) were aged 1 ≥year.[4]

CI, confidence interval; **FAQ,** frequently asked question; **RSV,** respiratory syncytial virus.

"Can't I wait until my baby is older to immunise them?"

- A baby's **first RSV season** is the period of **greatest risk of severe disease**,[4,9,10] because their immune systems are still maturing and their airways still developing[11]
  - This means they can't develop enough effective antibodies to protect against RSV[12,13]
- Giving babies antibodies by injection can help protect them during this time[14]

1. Piedimonte G and Perez MK. Pediatr Rev 2014; 35(12): 519–530. 2. Meissner HC. N Engl J Med 2016; 374(1): 62–72. 3. McLaughlin JM et al. J Infect Dis 2022; 225(6): 1100–1111. 4. Demont C et al. BMC Infect Dis 2021; 21(1): 730. 5. Reeves RM et al. J Infect 2019; 78(6): 468–475. 6. Bianchini S et al. Microorganisms 2020; 8(12): 2048. 7. Mira-Iglesias A et al. Influenza Other Respir Viruses 2022; 16(2): 328–339. 8. Health Protection Surveillance Centre (HPSC). Respiratory Syncytial Virus (RSV). Available at: https://www.hpsc.ie/a-z/respiratory/respiratorysyncytialvirus/ factsheet/. Accessed: August 2024. 9. Arriola C et al. J Pediatric Infect Dis Soc 2020; 9(5): 587–595 & Supplementary Appendix. 10. Hartmann K et al. J Infect Dis 2022; 226(3): 386–395. 11. Pickles RJ and DeVincenzo JP. J Pathol 2015; 235(2): 266–276. 12. Simon AK et al. Proc Biol Sci 2015; 282(1821): 20143085. 13. Lambert L et al. Front Immunol 2014; 5: 466. 14. Beyfortus® IE Package leaflet: Information for the user. September 2024.

Parent FAQs:

“Is it okay for my baby to have all these immunisations at once?”

- Explain that some immunisations are vaccines, and that **Beyfortus® is a preventative antibody** against RSV, not a vaccine[1]
- Beyfortus® **can** be given at the **same time** as vaccines included in the national immunisation programme[1]

"What's the difference between a preventative antibody and a vaccine?"

- When a germ infects the body, **antibodies** are produced to **help fight** against it[2]
- A vaccine is like learning **self-defense**; they teach the immune system to make its own antibodies[3]
- Preventative antibodies are not the same as vaccines.[3] They are given by injection and don't rely on the immune system as the **antibody is directly provided**[3]

1. Beyfortus® IE Package leaflet: Information for the user. September 2024.
2. Simon AK et al. Proc Biol Sci 2015; 282(1821): 20143085. 3. Centers for Disease Control and Prevention (CDC). Explaining how vaccines work. Available at: https://www.cdc.gov/vaccines/hcp/conversations/understanding-vacc-work.html. Accessed: August 2024.

FAQ, frequently asked question; **RSV,** respiratory syncytial virus.

Beyfortus® (nirsevimab)

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Prescribing Information

Prescribing Information: Beyfortus▼ (nirsevimab) solution for injection in pre-filled syringe Please refer to the Summary of Product Characteristics (SmPC) before prescribing

Presentation: Beyfortus 50 mg solution for injection in pre-filled syringe. Each pre-filled syringe contains 50 mg of nirsevimab in 0.5 mL (100 mg/mL). **Beyfortus 100 mg solution for injection in pre-filled syringe.** Each pre-filled syringe contains 100 mg of nirsevimab in 1 mL (100 mg/mL). Nirsevimab is a human immunoglobulin G1 kappa (IgG1κ) monoclonal antibody produced in Chinese hamster ovary (CHO) cells by recombinant DNA technology. Excipients with known effect: This medicine contains 0.1 mg of polysorbate 80 (E433) in each 50 mg (0.5 mL) dose and 0.2 mg in each 100 mg (1 mL) dose (see SmPC).
Indication: Beyfortus is indicated for the prevention of Respiratory Syncytial Virus (RSV) lower respiratory tract disease in: i. Neonates and infants during their first RSV season. ii. Children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season (see SmPC). Beyfortus should be used in accordance with official recommendations.
Dosage and Administration: *Infants during their first RSV season:* Beyfortus is recommended as a single dose of 50 mg administered intramuscularly for infants with body weight <5 kg and a single dose of 100 mg administered intramuscularly for infants with body weight ≥5 kg. Beyfortus should be administered from birth for infants born during the RSV season. For others born outside the season Beyfortus should be administered ideally prior to the RSV season. Dosing in infants with a body weight from 1 kg to <1.6 kg is based on extrapolation, no clinical data are available. Exposure in infants <1 kg is anticipated to yield higher exposures than in those weighing more. The benefits and risks of nirsevimab use in infants <1 kg should be carefully considered. There are limited data available in extremely preterm infants (Gestational Age [GA] <29 weeks) less than 8 weeks of age. No clinical data available in infants with a postmenstrual age (gestational age at birth plus chronological age) of less than 32 weeks (see SmPC). *Children who remain vulnerable to severe RSV disease through their second RSV season:* The recommended dose is a single dose of 200 mg given as two intramuscular injections (2 x 100 mg). Beyfortus should be administered ideally prior to the start of the second RSV season. For individuals undergoing cardiac surgery with cardiopulmonary bypass, an additional dose may be administered as soon as the individual is stable after surgery to ensure adequate nirsevimab serum levels. If within 90 days after receiving the first dose of Beyfortus, the additional dose during the first RSV season should be 50 mg or 100 mg according to body weight, or 200 mg during the second RSV season. If more than 90 days have elapsed since the first dose, the additional dose could be a single dose of 50 mg regardless of body weight during the first RSV season, or 100 mg during the second RSV season, to cover the remainder of the RSV season. Beyfortus is for intramuscular injection only. It is administered intramuscularly, preferably in the anterolateral aspect of the thigh. The gluteal muscle should not be used routinely as an injection site because of the risk of damage to the sciatic nerve. If two injections are required, different injection sites should be used. The safety and efficacy of nirsevimab in children aged 2 to 18 years have not been established. No data are available.
Contraindications: Hypersensitivity to the active substance or to any of the excipients listed in SmPC.
Warnings and precautions: *Hypersensitivity including anaphylaxis:* Serious hypersensitivity reactions have been reported following Beyfortus administration. Anaphylaxis has been observed with human immunoglobulin G1 (IgG1) monoclonal antibodies. If signs and symptoms of anaphylaxis or other clinically significant hypersensitivity reaction occur, immediately discontinue administration and initiate appropriate medicinal products and/or supportive therapy. *Clinically significant bleeding disorders:* As with any other intramuscular injections, nirsevimab should be given with caution to individuals with thrombocytopenia or any coagulation disorder. *Immunocompromised children:* In some immunocompromised children with protein-losing conditions, a high clearance of nirsevimab has been observed in clinical trials (see SmPC), and nirsevimab may not provide the same level of protection in those individuals. *Polysorbate 80 (E433):* This medicine contains 0.1 mg of polysorbate 80 in each 50 mg (0.5 mL) dose and 0.2 mg in each 100 mg (1 mL) dose. Polysorbates may cause allergic reactions.
Interactions: No interaction studies have been performed. Nirsevimab does not interfere with reverse transcriptase polymerase chain reaction (RT PCR) or rapid antigen detection RSV diagnostic assays that employ commercially available antibodies targeting antigenic site I, II, or IV on the RSV fusion (F) protein. *Concomitant administration with vaccines:* Since nirsevimab is a monoclonal antibody, a passive immunisation specific for RSV, it is not expected to interfere with the active immune response to co administered vaccines. There is limited experience of co administration with vaccines. In clinical trials, when nirsevimab was given with routine childhood vaccines, the safety and reactogenicity profile of the co administered regimen was similar to the childhood vaccines given alone. Nirsevimab can be given concomitantly with childhood vaccines. Nirsevimab should not be mixed with any vaccine in the same syringe or vial (see SmPC). When administered concomitantly with injectable vaccines, they should be given with separate syringes and at different injection sites.
Fertility, pregnancy and lactation: Not applicable.
Adverse Reactions: Uncommon (≥1/1,000 to <1/100): The most frequent adverse reaction was rash (0.7%) occurring within 14 days post dose. Additionally, within 7 days post-dose, pyrexia and injection site reactions were reported in 0.5% (0.6% in placebo) and 0.3% (0% in placebo) of nirsevimab recipients, respectively. Other Serious Adverse Drug Reactions: Not known (cannot be estimated from available data): hypersensitivity. Prescribers should consult the SmPC in relation to other adverse reactions.
Legal Category: POM
Marketing Authorisation Number:
EU/1/22/1689/001-002, EU/1/22/1689/004-005
Marketing Authorisation Holder:
Sanofi Winthrop Industrie, 82 avenue Raspail, 94250 Gentilly, France Further information is available from: IE: Sanofi, 18 Riverwalk, Citywest Business Campus, Dublin 24 or contact IEmedinfo@sanofi.com
Date of preparation: September 2024

Adverse events should be reported. Reporting forms and information can be found at www.hpra.ie; email: medsafety@hpra.ie Adverse events should also be reported to Sanofi Ireland Ltd. Tel: 01 403 5600.

Alternatively, send via email to IEPharmacovigilance@sanofi.com