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

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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