Beyfortus® (nirsevimab)

NAME OF THE MEDICINAL PRODUCT: *Beyfortus 50 mg solution for injection in pre-filled syringe Beyfortus 100 mg solution for injection in pre-filled syringe.*

QUALITATIVE AND QUANTITATIVE COMPOSITION*: 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.*

PHARMACEUTICAL FORM*: Solution for injection (injection). Clear to opalescent, colorless to yellow, pH 6.0 solution.*

Therapeutic indications: *Beyfortus is indicated for the prevention of Respiratory Syncytial Virus (RSV) lower respiratory tract disease in neonates and infants during their first RSV season. Beyfortus should be used in accordance with official recommendations.*

Posology*: The recommended dose is 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 prior to commencement of the RSV season, or from birth for infants born during the RSV season. The safety and efficacy of nirsevimab in children aged 2 to 18 years have not been established. No data are available.*

Method of administration*: 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.*

Contraindications*: Hypersensitivity to the active substance or to any of the excipients.*

Special warnings and precautions for use*: In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded. Hypersensitivity including anaphylaxis. As with any other intramuscular injections, nirsevimab should be given with caution to infants with thrombocytopenia or any coagulation disorder.*

Interaction with other medicinal products and other forms of interaction: *No interaction studies have been performed. Monoclonal antibodies do not typically have significant interaction potential, as they do not directly affect cytochrome P450 enzymes and are not substrates of hepatic or renal transporters. Indirect effects on cytochrome P450 enzymes are unlikely as the target of nirsevimab is an exogenous virus.*

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. Nirsevimab can be given concomitantly with childhood vaccines. Nirsevimab 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.*

Special precautions for storage: *Store in a refrigerator (2°C - 8°C). Do not freeze. Do not shake or expose to direct heat. Keep the pre-filled syringe in the outer carton in order to protect from light.*

Abbreviated Prescribing Information is based on SmPC, 2023.