For the use only of a Registered Medical Practitioner or a Hospital or Laboratory
This package insert is continually updated. Please read carefully before using a new pack
WARNING: To be sold by retail on the prescription of a Neonatologist or Pediatrician only

Abridged Prescribing Information

Nirsevimab solution for injection in pre-filled syringe
BEYFORTUS®

QUALITATIVE & QUANTITATIVE COMPOSITION:

Nirsevimab solution for injection in pre-filled syringe 50mg
Each pre-filled syringe contains:
Nirsevimab IH….....50 mg
L-Histidine USP-NF/ Ph. Eur./ JP…..... 1.1 mg
L-Histidine hydrochloride monohydrate Ph. Eur./ JP…..1.6 mg
L-Arginine hydrochloride USP-NF/ Ph. Eur./ JP..... 8 mg
Sucrose USP-NF/ Ph. Eur./ JP ..... 21 mg
Polysorbate 80 USP-NF/ Ph. Eur./ JP .....0.1 mg
Water for injection (WFI) USP-NF/ Ph. Eur./ JP…..... Approx. 440 mg

Nirsevimab solution for injection in pre-filled syringe 100mg
Each pre-filled syringe contains:
Nirsevimab IH….....100 mg
L-Histidine USP-NF/ Ph. Eur./ JP…..... 2.2 mg
L-Histidine hydrochloride monohydrate Ph. Eur./ JP….....3.3 mg
L-Arginine hydrochloride USP-NF/ Ph. Eur./ JP..... 17 mg
Sucrose USP-NF/ Ph. Eur./ JP ..... 41 mg
Polysorbate 80 USP-NF/ Ph. Eur./ JP .....0.2 mg
Water for injection (WFI) USP-NF/ Ph. Eur./ JP… Approx. 880 mg

THERAPEUTIC INDICATIONS: 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.

POSOLOGY AND METHOD OF ADMINISTRATION:

Neonates and Infants: First RSV Season

The recommended dosage of BEYFORTUS® for neonates and infants born during or entering their first RSV season is based on body weight (see Table 1) and is administered as a single intramuscular (IM) injection.

Table 1: Recommended Dosage of BEYFORTUS® in Neonates and Infants Born During or Entering Their First RSV Season

Body Weight at Time of Dosing	**Recommended Dosage**
Less than 5 kg	50 mg by IM injection
5 kg and greater	100 mg by IM injection

Children Who Remain at Increased Risk for Severe RSV Disease: Second RSV Season
For children up to 24 months of age who remain at increased risk for severe RSV disease in their second RSV season, the recommended dosage of BEYFORTUS® is a single 200 mg dose administered as two IM injections (2 x 100 mg).

Administration Instructions for Single-Dose Pre-filled Syringe:

Step 1: Holding the Luer lock in one hand (avoid holding the plunger rod or syringe body), unscrew the syringe cap by twisting it counter-clockwise with the other hand.

Step 2: Attach a Luer lock needle to the pre-filled syringe by gently twisting the needle clockwise onto the pre-filled syringe until slight resistance is felt.

Step 3: Hold the syringe body with one hand and carefully pull the needle cover straight off with the other hand. Do not hold the plunger rod while removing the needle cover or the rubber stopper may move. Do not touch the needle or let it touch any surface. Do not recap the needle or detach it from the syringe.

Step 4: Administer the entire contents of the BEYFORTUS® pre-filled syringe as an IM injection, preferably in the anterolateral aspect of the thigh. The gluteal muscle should not be used as an injection site because of the risk of damage to the sciatic nerve.

Step 5: Discard syringe into a sharps container.

If two injections are required, repeat Steps 1-5 in a different injection site.

CONTRAINDICATIONS: BEYFORTUS® is contraindicated in infants and children with a history of serious hypersensitivity reactions, including anaphylaxis, to Nirsevimab or to any of the excipients.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE: Hypersensitivity Including Anaphylaxis- Serious hypersensitivity reactions, including anaphylaxis, have been observed with other human immunoglobulin G1 (IgG1) monoclonal antibodies. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, initiate appropriate medications and/or supportive therapy. **Use in Individuals with Clinically Significant Bleeding Disorders-** As with any other IM injections, BEYFORTUS® should be given with caution to infants and children with thrombocytopenia, any coagulation disorder, or to individuals on anticoagulation therapy.

DRUG INTERACTIONS: Interference with RT-PCR or Rapid Antigen Detection RSV Diagnostic Assays- BEYFORTUS® 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. For immunological assay results which are negative when clinical observations are consistent with RSV infection, it is recommended to confirm using an RT-PCR-based assay.

PREGNANCY AND LACTATION: Pregnancy- BEYFORTUS® is not indicated for use in females of reproductive potential. **Lactation-** BEYFORTUS® is not indicated for use in females of reproductive potential.

UNDESIRABLE EFFECTS: Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

OVERDOSE: There is limited experience of overdose with BEYFORTUS®.There is no specific treatment for an overdose with BEYFORTUS®. In the event of an overdose, the individual should be monitored for the occurrence of adverse reactions and provided with symptomatic treatment as appropriate.

PHARMACODYNAMIC PROPERTIES: There is a positive correlation between a serum nirsevimab AUC (based on clearance at baseline) above 12.8 mg*day/mL and a lower incidence of medically attended RSV lower respiratory tract infection (MA RSV LRTI). Following IM administration of nirsevimab in adults, RSV neutralizing antibody levels in serum were approximately 4 times higher than baseline at 8 hours after nirsevimab dosing, and maximum levels were reached by day 6 following IM administration of nirsevimab in adults. The safety and effectiveness of BEYFORTUS® have not been established in adults.

Duration of Protection- Based on clinical data, the duration of protection offered by a single dose of BEYFORTUS® extends through 5 months.

For full prescribing information, please contact Sanofi Healthcare India Pvt. Ltd., Sanofi House, CTS No. 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai 400072 – India

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