נובמבר 2024

Beyfortus (Solution for Injection)

חומר פעיל:

NIRSEVIMAB 100 MG / 1 ML

ההתוויה המאושרת:

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.

חברת סאנופי מבקשת להודיע על עדכון העלון לצרכן במתכונת עלון לרופא.

העדכונים העיקריים הינם:

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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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 section 4.4).
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4.4 Special warnings and precautions for use

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Hypersensitivity including anaphylaxis

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

Greenwork Park, Yakum, Building E, 1st floor, 6097600, Israel
Tel.: +972-9-8633081 - Fax: +972-9-8851444 - www.sanofi.co.il

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4.8 Undesirable effects

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Tabulated list of adverse reactions

Table 1 presents the adverse reactions reported in 2 966 term and preterm infants (GA ≥29 weeks) who received nirsevimab in clinical trials and in post-marketing setting (see section 4.4).

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Table 1: Adverse reactions

MedDRA SOC	MedDRA Preferred Term	Frequency
Immune system disorders	Hypersensitivity[a]	Not known
Skin and subcutaneous tissue disorders	~~Rash~~[a]Rash[b]	Uncommon
General disorders and administration site conditions	Injection site ~~reaction~~[b]reaction[c]	Uncommon
	Pyrexia	Uncommon

[a] Adverse reaction from spontaneous reporting.

~~[a]~~[b] Rash was defined by the following grouped preferred terms: rash, rash maculo-papular, rash macular.

~~[b]~~[c] Injection site reaction was defined by the following grouped preferred terms: injection site reaction, injection site pain, injection site induration, injection site oedema, injection site swelling.

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5.2 Pharmacokinetic properties

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Pharmacokinetic/pharmacodynamic relationship(s)

In D5290C00003 and MELODY (Primary cohort) a positive correlation was observed between a serum AUC (Area Under the Curve), ~~(~~based on clearance at baseline~~,)~~ above 12.8 ~~mg~~ mg*day/mL and a lower incidence of MA RSV LRTI. The recommended dosing regimen consisting of a 50 mg or 100 mg intramuscular dose for infants in their first RSV season and a 200 mg intramuscular dose for children entering their second RSV season was selected on the basis of these results.

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העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס על ידי פנייה לבעל הרישום - סאנופי ישראל בע"מ, Greenwork Park, מתחם העסקים בקיבוץ יקום, בניין E (קומה 1), 6097600, יקום או בטלפון: 09-8633081.

להלן הקישור לאתר משרד הבריאות: https://israeldrugs.health.gov.il/#!/byDrug

בברכה,

חברת סאנופי ישראל בע"מ