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SYNAGIS® PALIVIZUMAB

SYNAGIS TO BE VOLUNTARILY DISCONTINUED

Dear Payer,

We are writing to inform you that Sobi is voluntarily **discontinuing the availability of SYNAGIS for RSV prophylaxis as of December 31, 2025**. Effective that date, the product will no longer be manufactured, distributed, or available for purchase. This discontinuation applies to all settings of care and indicated patient populations, including infants with a history of premature birth (<35 weeks gestational age), those with bronchopulmonary dysplasia (BPD), and those with congenital heart disease (CHD).

Removal of SYNAGIS from the US market is not expected to adversely affect patients due to available treatment alternatives including nirsevimab and clesrovimab.

Thank you for your continued dedication to the health of vulnerable infants.

If you have any questions,
contact Sobi Medical Affairs
or call 1-866-773-5274.

INDICATION

SYNAGIS, 50 mg and 100 mg for injection, is indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients:

- with a history of premature birth (≤35 weeks gestational age) and who are 6 months of age or younger at the beginning of RSV season
- with bronchopulmonary dysplasia (BPD) that required medical treatment within the previous 6 months and who are 24 months of age or younger at the beginning of RSV season
- with hemodynamically significant congenital heart disease (CHD) and who are 24 months of age or younger at the beginning of RSV season

LIMITATIONS OF USE

The safety and efficacy of SYNAGIS have not been established for treatment of RSV disease.

CONTRAINDICATIONS

Previous significant hypersensitivity reaction to SYNAGIS.

IMPORTANT SAFETY INFORMATION

Hypersensitivity Reactions: Anaphylaxis and anaphylactic shock (including fatal cases) and other severe acute hypersensitivity reactions have been reported. Permanently discontinue SYNAGIS and administer appropriate medication if such reactions occur.

Coagulation Disorders: SYNAGIS should be given with caution to children with thrombocytopenia or any coagulation disorder.

RSV Diagnostic Test Interference: Palivizumab may interfere with immunological-based RSV diagnostic tests, such as some antigen detection-based assays.

Serious Adverse Reactions: The most common serious adverse reactions occurring with SYNAGIS are anaphylaxis and other acute hypersensitivity reactions.

Most Common Adverse Reactions: The most common adverse reactions are fever and rash.

Postmarketing Experience: Severe thrombocytopenia and injection site reactions have been identified during post approval use of SYNAGIS.

Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

These are not all the possible risks associated with SYNAGIS.

Please see full Prescribing Information for SYNAGIS, including Patient Information.

To report suspected adverse reactions, contact Sobi North America at 1-866-773-5274 or the FDA at 1-800-FDA-1088.

RSV=respiratory syncytial virus.

Regards,
The Sobi Team

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sobi rare strength