



**MedImmune, Inc.**

November 26, 2002

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<p style="text-align: center;"><b>IMPORTANT PRESCRIBING INFORMATION</b></p>
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Dear Healthcare Professional:

MedImmune, Inc. would like to update you on several changes to the prescribing information for Synagis<sup>®</sup> (palivizumab).

The Warnings section of the updated Synagis<sup>®</sup> label has been changed to provide clarification on the risk of anaphylaxis. At the time Synagis was licensed, there were no observed cases of anaphylaxis. However, because of the protein nature of the product such reactions could be anticipated and was presented as a theoretical risk statement in the Warnings section.

Post licensure, information based on four seasons of worldwide post-marketing experience representing over 400,000 patients and 2,000,000 doses administered have been reviewed, and a total of 2 patients with anaphylaxis have been reported. Both patients made a full recovery with appropriate therapy. Because the risk of anaphylaxis has changed from a theoretical to an actual, but very rare occurrence, the WARNINGS section has been modified to read:

*“Very rare cases of anaphylaxis (<1 case per 100,000 patients) have been reported following re-exposure to Synagis (palivizumab) [see Adverse Reactions, Post-Marketing Experience]. Rare severe acute hypersensitivity reactions have also been reported on initial exposure or re-exposure to palivizumab. If a severe hypersensitivity reaction occurs, therapy with palivizumab should be permanently discontinued. If milder hypersensitivity reactions occur, caution should be used on readministration of palivizumab. **If anaphylaxis or severe allergic reactions occur, administer appropriate medications (e.g., epinephrine) and provide supportive care as required.**”*

Additionally, based on the review of post marketing patient exposure data beyond 5 doses the OVERDOSAGE section of the prescribing information has been changed to remove the following statement:

*“No data are available from human subjects who have received more than 5 monthly Synagis (palivizumab) doses during a single RSV season.”*

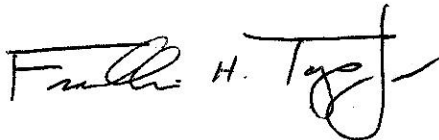
Upon review of the post marketing data for patient exposure beyond 5 doses in a single RSV season, we have found that adverse events after a sixth or greater dose of Synagis<sup>®</sup> (palivizumab) are similar in character and frequency to those after the initial five doses. Therefore, the following statement was added to the Adverse Reactions, Post Marketing Experience section of the labeling:

*“Limited information from post-marketing reports suggests that, within a single RSV season, adverse events after a sixth or greater dose of Synagis<sup>®</sup> (palivizumab) are similar in character and frequency to those after the initial five doses.”*

Healthcare professionals are encouraged to report any serious adverse event that occurs with the use of Synagis to MedImmune, Inc, Pharmacovigilance Unit at (301) 527-4569, (800)-949-3789 or to the FDA’s MedWatch program by phone (1-800-FDA-1088), fax (1-800-FDA-0178), via the MedWatch website ([www.FDA.gov/medwatch](http://www.FDA.gov/medwatch)), or by mail (using postage paid and the FDA-3500 form) to MedWatch, HF-2, 5600 Fisher’s Lane, Rockville, MD 20852-9787.

A copy of Synagis full Prescribing Information is enclosed for your reference. If you have any further questions regarding Synagis, please feel free to call MedImmune, Inc. Medical Information Services at 1-877-633-4411.

Sincerely,

A handwritten signature in black ink, appearing to read "Franklin H. Taylor". The signature is fluid and cursive, with a long horizontal stroke at the end.

Franklin H. Taylor, M.D.  
Executive Vice President and Medical Director  
MedImmune, Inc.