August 26, 2005

IMMEDIATE ATTENTION REQUIRED

DISPENSING ERROR ALERT

Dear Pharmacist:

As your partner in diabetes care, Novo Nordisk Inc. recognizes the importance of patient safety and proper medication dispensing. We would like to make you aware of a recent initiative we have implemented to help prevent dispensing errors. Color branded labeling has been introduced for our insulin analog line, **NovoLog® Mix 70/30** (70% insulin aspart protamine suspension and 30% insulin aspart injection, [rDNA origin]) and **NovoLog®** (insulin aspart [rDNA origin] injection). Until recently, the labeling for these two products was very similar, with the exception of the product names. It is important that all pharmacists **carefully distinguish insulin formulations by name and NDC number** when dispensing. Patients receiving the incorrect insulin could be subject to the risk of adverse events, such as hyperglycemia or hypoglycemia. The use of color branded labeling will aid in facilitating dispensing of the correct product.

NovoLog® Mix 70/30
NovoLog Mix 70/30 is a premixed insulin analog. **NovoLog Mix 70/30** is available in 10 mL vials, one package of 5 **NovoLog Mix 70/30 FlexPen**® prefilled syringes as well as one package of 5 PenFill® cartridges. **NovoLog Mix 70/30** is a white suspension that becomes cloudy when mixed. The previous box for **NovoLog Mix 70/30** is white with a blue band. The current packaging for **NovoLog Mix 70/30** is very similar and remains white with a blue band (see inset photo for current packaging).

NovoLog Mix 70/30 is indicated for the treatment of patients with diabetes mellitus for the control of hyperglycemia. Because **NovoLog Mix 70/30** has peak pharmacodynamic activity 1 hour after injection, it should be administered with meals. Hypoglycemia is the most common adverse effect of insulin therapy, including **NovoLog Mix 70/30**. **NovoLog Mix 70/30** is contraindicated during episodes of hypoglycemia and in patients hypersensitive to **NovoLog Mix 70/30** or one of its excipients. Potential side effects associated with the use of all insulins include hypoglycemia, hypokalemia, lipodystrophy, and allergic reactions. Because of differences in the action of **NovoLog Mix 70/30** and other insulins, care should be taken in patients in whom these conditions may be clinically relevant (eg, patients who are fasting, have autonomic neuropathy, are using potassium-lowering drugs, or are taking drugs sensitive to serum potassium level). Do not mix **NovoLog Mix 70/30** with any other insulin product.

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NovoLog®
NovoLog is a rapid-acting insulin analog. **NovoLog** is available in 10 mL vials, one package of 5 **NovoLog FlexPen®** prefilled syringes as well as one package of 5 PenFill® cartridges. **NovoLog** is a clear and colorless solution. The previous box for **NovoLog** is white with a blue band. The current packaging for **NovoLog** is white with an orange band (see inset photo for current packaging).

NovoLog is indicated for the treatment of adult patients with diabetes mellitus for the control of hyperglycemia. **NovoLog** has a more rapid onset and shorter duration of action than regular human insulin. Because of the fast onset of action, the injection of **NovoLog** should immediately be followed by a meal. Because of the short duration of action of **NovoLog**, patients with diabetes also may require a longer-acting insulin to maintain adequate glucose control. **NovoLog** is contraindicated during episodes of hypoglycemia and in patients hypersensitive to **NovoLog** or one of its excipients.

Any change in insulin should be made cautiously and only under medical supervision.

Your Role in Patient Safety

Novo Nordisk offers the following recommendations to help reduce the potential for dispensing errors:

- Confirm that the product name on the prescription and store printed pharmacy label match the name on the product dispensed.
- If you remove the insulin from the box for any reason, be sure to put it back in the exact same box.
- Separate medications with similar names from one another where they are stored.
- Ensure that the patient is knowledgeable about the insulin name and type that was prescribed by his/her healthcare professional.
- Have the patient check the insulin name and type when picking up their prescription.
- Instruct the patient to speak with a pharmacist immediately regarding any problems, questions or concerns they may have about their medication.
- Provide counseling on how to use the medication properly.

We appreciate your assistance with helping to prevent dispensing errors. If you become aware of a prescription dispensing error involving **NovoLog Mix 70/30** or **NovoLog**, please contact Novo Nordisk immediately at 1-800-727-6500 or contact the USP Medication Errors Reporting Program at 1-800-233-7767 or the FDA MeDWATCH program by telephone at 1-800-FDA-1088, fax at 1-800-FDA-0178 or online at http://www.fda.gov/medwatch.

Thank you for your support and cooperation.

Sincerely,

MD

Nilima Justice, MD
Senior Director, Product Safety Surveillance
Novo Nordisk Inc.

Please see enclosed full prescribing information for NovoLog Mix 70/30 and NovoLog.