

Dear Doctor,

**Re: Discontinuation of Regular Iletin[®] II (INSULIN INJECTION, USP, PURIFIED PORK)
and NPH Iletin[®] II (ISOPHANE INSULIN SUSPENSION, USP, PURIFIED PORK)**

After thoughtful consideration, Eli Lilly and Company has decided to stop producing Regular Iletin[®] II Pork and NPH Iletin[®] II Pork Insulins. While over 3.5 million patients with diabetes in the U.S. currently use insulin, it is estimated that approximately 2000 patients remain on Regular Iletin II Pork and NPH Iletin II Pork Insulins. Newer insulin therapies have increased the number of treatment options available for patients and have resulted in a continually declining use of both Iletin products.

Our first priority is to make certain that patients transition as smoothly as possible to an alternative insulin therapy, regardless of whether the new therapy is a Lilly insulin or not. Lilly is notifying physicians, other healthcare professionals, diabetes associations, and patients regarding the timing for the discontinuation to allow affected patients sufficient time to transfer to alternate insulin formulations or treatments.

Based on current demand and our current stock of Regular Iletin II Pork and NPH Iletin II Pork Insulin, Lilly anticipates that vials of both products will be available in pharmacies until the end of 2005. All vials of both insulins shipped from Lilly after mid-August 2005 will have the following notice printed on the carton: REGULAR Pork Iletin[®] II and NPH Pork Iletin[®] II (are) being discontinued. Contact your physician to change to another insulin. For information call 1-800-545-5979.

Lilly is recommending to patients who are currently using Regular Iletin II Pork and/or NPH Iletin II Pork insulins that they see their physician so that appropriate changes to their insulin treatment can be made. Healthcare providers should consider switching patients on Regular Iletin II Pork Insulin to Regular human insulin or a rapid-acting insulin analog. Patients on NPH Iletin II Pork Insulin may be switched to NPH human insulin or a basal insulin analog. Careful monitoring of blood glucose levels and adjustments to insulin therapy are important when switching patients, in addition to the other standard recommendations concerning diabetes care (1).

Considering the lower immunogenic response with human insulin, patients who change to human insulin and require more than 100 units per day of animal source insulin may require a lower dose of human insulin (2,3). This dose may be 10% to 20% less than the animal insulin dose. Considering the more rapid onset of action with rapid-acting insulin analogs, patients who change from Regular Iletin II Pork Insulin to a rapid-acting insulin analog will need to be counseled to adjust their timing of insulin injection with relation to meals.

To assist you in communicating information concerning this product discontinuation to your patients who use Regular Iletin II Pork and NPH Iletin II Pork Insulin, enclosed are copies of the patient information sheet. The sheet will inform patients about the discontinuation and provide answers to frequently asked questions. To avoid confusion, please be sure to distribute the sheet only to patients currently using Regular Iletin II Pork and NPH Iletin II Pork Insulin. Also enclosed are 5 LillyScripts for redemption on any Lilly insulin product to help facilitate transition of affected patients.

You can also find the patient information sheets online. Physicians can visit www.LillyConnect.com and direct patients to www.LillyDiabetes.com.

Again, our first priority is to make certain that patients transition as smoothly as possible to an alternative insulin therapy, regardless of whether the new therapy is a Lilly insulin or not.

For additional information, Lilly is available to answer your questions at 1-800-LillyRx (1-800-545-5979) from 9:00am to 5:00pm Eastern Time, Monday through Friday.

Sincerely,



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1. American Diabetes Association. Standards of medical care for patients with diabetes mellitus. *Diabetes Care*. 2005; 28 (suppl 1); S4-36.
2. Davidson JA. Recombinant DNA human insulin: Clinical experience with the transfer of diabetic patients from animal source insulins. *Resident and Staff Physician* 1989;35:39-47.
3. Fletcher JA, Barnett DA, Pyke DA et al. Transfer from animal insulins to semisynthetic human insulin: a study in four centers. *Diabetes Research* 1990; 14:151-8.

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