

Lilly will no longer be manufacturing the original Prefilled Pen that contains Humalog® (insulin lispro injection [rDNA origin]), Humalog® Mix75/25™ (75% insulin lispro protamine suspension, 25% insulin lispro injection [rDNA origin]), and Humalog® Mix50/50™ (50% insulin lispro protamine suspension, 50% insulin lispro injection [rDNA origin]) as of January 1, 2011.

In addition, there is currently a limited supply of the original Prefilled Pen devices containing the Humalog brand of insulin, which could mean that they may not be available at some pharmacies as early as summer 2010.

The limited supply is for the original Prefilled Pen devices only. The Humalog brand of insulin remains available in other delivery options including Humalog® KwikPen™, Humalog® Mix75/25™ KwikPen™, and Humalog® Mix50/50™ KwikPen™, as well as vials.

Dear Healthcare Professional:

About two years ago, Lilly launched the Humalog KwikPen, Humalog Mix75/25 KwikPen, and Humalog Mix50/50 KwikPen. In an effort to align all Humalog prefilled devices under a single pen platform, the original Prefilled Pen containing the Humalog brand of insulin will no longer be manufactured after January 1, 2011.

Humalog KwikPen, Humalog Mix75/25 KwikPen, and Humalog Mix50/50 KwikPen, as well as vials that contain the Humalog brand of insulin will continue to remain available and are not affected by the discontinuation or by supply limitations.

The availability of the original Prefilled Pen containing the Humalog brand of insulin will depend on individual pharmacies' stock.

As a result, you may want to begin speaking now with your patients who use the original Prefilled Pen containing the Humalog brand of insulin about alternative options for their insulin therapy delivery device.

We do not currently anticipate any general supply limitations for Humulin® N (NPH human insulin [rDNA origin] isophane suspension) or Humulin® 70/30 (70% human insulin isophane suspension, 30% human insulin injection [rDNA origin]) in the original Prefilled Pen. We plan to continue manufacturing these options into 2011.

Enclosed is an information card for you, as well as a document that outlines some patient frequently asked questions for you to share with users of the original Prefilled Pen containing the Humalog brand of insulin.

Humalog, Humalog Mix75/25, and Humalog Mix50/50 are for use in patients with diabetes mellitus for the control of hyperglycemia. Humalog should be used with longer-acting insulin, except when used in combination with sulfonylureas in patients with type 2 diabetes.

Select Safety Information: Hypoglycemia is the most common adverse effect associated with insulins, including the Humalog brand of insulin. Humalog, Humalog Mix75/25, and Humalog Mix50/50 should be given within 15 minutes before a meal. Humalog can also be given immediately after a meal.

For complete safety profile, please see Important Safety Information on reverse and accompanying full Prescribing Information.

You may also visit Humalog.com/PenInfo or contact Eli Lilly and Company at 1-800-LillyRx (1-800-545-5979) with questions. For KwikPen™ insurance coverage in your area, visit Humalogavailability.com.

Sincerely,

Lilly USA, LLC


insulin lispro injection (rDNA origin)


75% insulin lispro protamine suspension
25% insulin lispro injection (rDNA origin)


50% insulin lispro protamine suspension
50% insulin lispro injection (rDNA origin)



Indication

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Important Safety Information

Contraindications

Humalog insulins are contraindicated during episodes of hypoglycemia and in patients sensitive to Humalog or one of its excipients.

Warnings

Humalog differs from regular human insulin by its rapid onset of action as well as a shorter duration of action. Therefore, when used as a mealtime insulin, Humalog insulins (Humalog, Humalog Mix75/25, and Humalog Mix50/50) should be given within 15 minutes before a meal. Humalog can also be given immediately after a meal.

Due to the short duration of action of Humalog, patients with type 1 diabetes also require a longer-acting insulin to maintain glucose control (except when using an insulin pump).

Glucose monitoring is recommended for all patients with diabetes.

The safety and effectiveness of Humalog in patients less than 3 years of age have not been established. Safety and effectiveness of Humalog Mix75/25 and Humalog Mix50/50 in patients less than 18 years of age have not been established. There are no adequate and well-controlled clinical studies of the use of Humalog insulins in pregnant or nursing women.

Starting or changing insulin therapy should be done cautiously and only under medical supervision.

Important Safety Information, continued

Warnings, continued

Patients should be advised not to mix Humalog Mix75/25 or Humalog Mix50/50 with another insulin.

Hypoglycemia

Hypoglycemia is the most common adverse effect associated with insulins, including Humalog insulins. Hypoglycemia can happen suddenly, and symptoms may be different for each person and may change from time to time. Severe hypoglycemia can cause seizures and may be life-threatening.

Other Side Effects

Other potential side effects associated with the use of insulins include: hypokalemia, weight gain, lipodystrophy, and hypersensitivity. Systemic allergy is less common, but may be life-threatening. Because of the difference in action of Humalog insulins, care should be taken in patients in whom hypoglycemia or hypokalemia may be clinically relevant (eg, those who are fasting, have autonomic neuropathy or renal impairment, are using potassium-lowering drugs, or taking drugs sensitive to serum potassium level).

For additional safety profile and other important prescribing considerations, see the accompanying full Prescribing Information.

Please see full user manual that accompanies the pen.

Humalog® and Humalog® KwikPen™ are registered trademarks of Eli Lilly and Company and are available by prescription only.

Humalog® Mix75/25™ and Humalog® Mix50/50™ are trademarks of Eli Lilly and Company and are available by prescription only.

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Humulin® is a registered trademark of Eli Lilly and Company.

Humalog

insulin lispro injection (rDNA origin)

Humalog^{mix} 75/25™

75% insulin lispro protamine suspension
25% insulin lispro injection (rDNA origin)

Humalog^{mix} 50/50™

50% insulin lispro protamine suspension
50% insulin lispro injection (rDNA origin)

Important Information regarding the upcoming discontinuation and current supply of the original Prefilled Pen containing the Humalog brand of insulin

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Original Prefilled Pen to be discontinued for Humalog brand of insulin



KwikPen™ remains available

Indication

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Select Safety Information

Hypoglycemia is the most common adverse effect associated with insulins, including the Humalog brand of insulin.

Humalog, Humalog Mix75/25, and Humalog Mix50/50 should be given within 15 minutes before a meal. Humalog can also be given immediately after a meal.

Please see Important Safety Information on reverse side and accompanying full Prescribing Information. Please see full user manual that accompanies the pen.

Humalog

insulin lispro injection (rDNA origin)

Humalog^{mix} 75/25

75% insulin lispro protamine suspension
25% insulin lispro injection (rDNA origin)

Humalog^{mix} 50/50

50% insulin lispro protamine suspension
50% insulin lispro injection (rDNA origin)

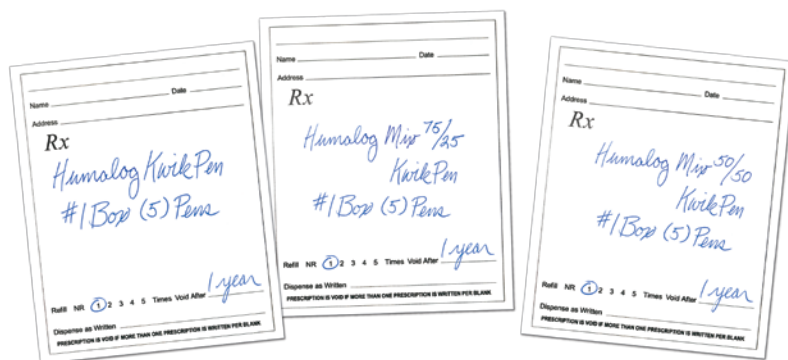
Lilly

What You Need To Know

- The original Prefilled Pen containing the Humalog brand of insulin will continue to be available until supplies are exhausted, which could occur as early as summer 2010, in some areas
- If pens are stored properly, patients can continue to use their original Prefilled Pen until the expiration date stamped on the carton and pen
- For most managed care and Medicare Part D plans, KwikPen is available at the same co-pay/tier as the original Prefilled Pen.* Since plans may vary, it is important to have your patients check with their plan if they have additional questions about their coverage
- Patients can continue to use the same Becton Dickinson needles with KwikPen that they used with the original Prefilled Pen
- As with the original Prefilled Pen, there is no refrigeration needed after first use of KwikPen. Please refer to the prescribing information accompanying this document for complete information regarding storage

You may also visit Humalog.com/PenInfo or contact Eli Lilly and Company at 1-800-LillyRx (1-800-545-5979) with questions. For KwikPen™ insurance coverage in your area, visit Humalogavailability.com.

*Data Source: MediMedia Information Technologies, Formulary Compass™, February 2010. ©2009 MediMedia USA, All Rights Reserved.



Please note:

When KwikPen prefilled with the Humalog brand of insulin is prescribed, a separate prescription for Becton Dickinson needles must be written.

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Starting or changing insulin therapy should be done cautiously and only under medical supervision.

Important Safety Information, continued

Warnings, continued

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