



Lilly Announces Launch of Color Differentiation System for Humalog(R) and Humulin(R) U-100 Insulin Products in the United States

Provides supplemental recognition factor to assist in product identification

INDIANAPOLIS, Oct 27, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- Eli Lilly and Company (NYSE: LLY) today announced the introduction of a color differentiation system for U-100 insulin products marketed in the United States, including vials, pens and individual packaging for Humalog(R) (insulin lispro injection [rDNA origin]) and Humulin(R) (regular insulin human injection, USP [rDNA origin]).

The Lilly color differentiation system - also used for Humalog and Humulin formulations marketed in Europe - follows the introduction of bar coding of packaging and insulin vials instituted in the U.S. by Lilly in 2004. Combined, these safety measures offer patients, physicians, pharmacists and other health care professionals a multi-tiered product identification and recognition system for Lilly's insulin products.

With color differentiation, the redesigned labeling can help patients, health care providers and pharmacists accurately identify the insulin that has been prescribed.

"Insulin is a powerful medicine that has an 85-year track record of efficacy and safety when administered and used properly. But if insulin is administered improperly, patients could be put at risk of serious injury because blood sugar levels may drop too low," said Sherry Martin, M.D., Associate Medical Director, Lilly USA. "Differentiating insulins with clearly printed labels and color-differentiated packaging has the potential to help reduce medication errors and improve safety for patients with diabetes. The use of color provides a supplemental recognition factor beyond the actual wording on the label. However, people should remember that color differentiation of insulin is not a substitute for reading the label carefully before using insulin."

The first device to be packaged in accordance with the new color differentiation system is Humalog(R) KwikPen(R), an insulin pen prefilled with the Humalog brand of insulins. Humalog KwikPen is designed to be convenient, easy to use and discreet, and its design can help fit a mealtime insulin, such as Humalog, into the daily lives and routines of people with diabetes. The Humalog brand of insulins is indicated for use in patients with diabetes to control high blood sugar. Humalog should be used with longer-acting insulin, except when used in combination with sulfonylureas in patients with type 2 diabetes.

Color differentiation of other Humalog and Humulin U-100 products, including vials, is being introduced throughout 2008. Colors indicate both insulin family and insulin type: burgundy for the Humalog family, blue for the Humulin family, and yellow for Regular insulin. For example, a blue-yellow combination would indicate Humulin-R. Insulin mixes will also be addressed with a two-color system. The products will be differentiated by the following colors:

Humalog (insulin lispro injection [rDNA origin]) = burgundy

Humalog Mix75/25 (75% insulin lispro protamine suspension, 25% insulin lispro injection [rDNA origin]) = burgundy and yellow

Humalog Mix50/50 (50% insulin lispro protamine suspension, 50% insulin lispro injection [rDNA origin]) = burgundy and red

Humulin 70/30 = dark blue and brown

Humulin R = dark blue and light yellow

Humulin N = dark blue and bright green

To learn more about color differentiation and insulin delivery devices for use with the Humalog brand of insulins, visit www.humalog.com

About the Humalog Brand of Insulins

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]) are for use in patients with diabetes to control high blood sugar. Humalog should be used with longer-acting insulin, except when used in combination with sulfonylureas in patients with type 2 diabetes.

Important Safety Information

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

Humalog is an injectable, fast-acting insulin. Humalog Mix75/25 and Humalog Mix50/50 are a mixture of fast-acting and longer-acting insulins. These insulins start working faster than other insulins that contain regular human insulin. Humalog, Humalog Mix75/25, and Humalog Mix50/50 should be taken within 15 minutes before a meal. Humalog can be taken right after eating a meal. Check your blood sugar levels as told by your healthcare professional.

If you have type 1 diabetes, you need to take a longer-acting insulin in addition to Humalog (except when using an external insulin pump). If you have type 2 diabetes, you may be taking diabetes pills and/or a longer-acting insulin in addition to Humalog.

The safety and effectiveness of Humalog in patients less than 3 years of age have not been established. The 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, Humalog Mix75/25, or Humalog Mix50/50 in pregnant or nursing women.

Humalog, Humalog Mix75/25, and Humalog Mix50/50 should not be used during episodes of low blood sugar (hypoglycemia) or if you are allergic to anything in these insulins.

Low Blood Sugar

Low blood sugar is the most common adverse effect associated with insulins, including Humalog, Humalog Mix75/25, and Humalog Mix50/50. Low blood sugar can happen suddenly, and symptoms may be different for each person and may change from time to time. Know your symptoms of low blood sugar. Severe low blood sugar can cause seizures and be life-threatening. Follow your healthcare professional's instructions for treating low blood sugar. Talk to your healthcare professional if low blood sugar is a problem for you.

Other Side Effects

Other potential side effects associated with the use of insulins include: low blood potassium, weight gain, changes in fat tissue at the injection site, and allergic reactions. Allergic reactions can happen at the site of injection and over the whole body. Whole body allergic reactions are less common, but may be life-threatening.

For other important information, see the accompanying Patient Information leaflet.

Please see full user manual that accompanies the Pen.

About Lilly Diabetes

For more than 85 years, Lilly has been a worldwide leader in pioneering industry-leading solutions to support people living with and treating diabetes. Lilly introduced the world's first commercial insulin in 1923, and remains at the forefront of medical and delivery device innovation to manage diabetes. Lilly is also committed to providing solutions beyond therapy -- practical tools, education and support programs to help overcome barriers to success along the diabetes journey. At Lilly, the journeys of each person living with or treating diabetes inspire ours. For more information, visit www.lillydiabetes.com.

About Eli Lilly and Company

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of first-in-class and best-in-class pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, Ind., Lilly provides answers -- through medicines and information -- for some of the world's most urgent medical needs. Information about Lilly is available at www.lilly.com.

Humalog(R) is a registered trademark of Eli Lilly and Company. Humalog(R) Mix75/25(TM) and Humalog(R) Mix50/50(TM) are trademarks of Eli Lilly and Company. Humalog(R) KwikPen(R) is a registered trademark of Eli Lilly and Company. Humulin(R) R Regular; Humulin(R) N NPH and Humulin(R) 70/30 are trademarks of Eli Lilly and Company.

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