A Proactive Approach to Type 2 Diabetes Management in Long-term Care Facilities

Presented by

Firas Akhrass, MD

Date

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Location

Biga on the Banks 203 S. St. Mary's Street San Antonio, Texas 78205

RSVP

To Arnold Bolado 210.393.9006

By Thursday, September 24, 2015

As a result of enacted state and federal legislation, if you are a prescriber or other licensed healthcare professional with an active license from MA, MN, and/or VT, a Veterans Affairs employee, and/or state government employee, you may be restricted from accepting industry-provided food/beverage and/or educational item(s). Please consult your state or federal regulations or ethics laws.

This program is intended only for invited healthcare professionals (HCPs) or other appropriate personnel for whom the information that is being presented will be relative to their practice. We regret that spouses or other guests cannot be accommodated.

Indication for Humalog, Humalog Mix75/25, and Humalog Mix50/50

•Humalog® is an insulin analog indicated to improve glycemic control in adults and children with diabetes mellitus. Humalog® Mix75/25™ and Humalog® Mix50/50™ are indicated in the treatment of adults with diabetes mellitus for the control of hyperglycemia.

Select Safety Information for Humalog, Humalog Mix75/25, and Humalog Mix50/50

• Humalog, Humalog Mix75/25, and Humalog Mix50/50 are contraindicated during episodes of hypoglycemia and in patients who are hypersensitive to insulin lispro or any excipients contained in the formulation.

Please see Important Safety Information on next page and accompanying Full Prescribing Information.

insulin lispro injection, USP (rDNA origin) 100 units/mL

75% insulin lispro protamine suspension 25% insulin lispro injection (rDNA origin) 100 units/ml

50% insulin lispro protamine suspension 50% insulin lispro injection (rDNA origin) 100 units/mL



Important Safety Information for Humalog, Humalog Mix75/25, and Humalog Mix50/50

Contraindications

• Humalog, Humalog Mix75/25, and Humalog Mix50/50 are contraindicated during episodes of hypoglycemia and in patients who are hypersensitive to insulin lispro or any excipients contained in the formulation.

Warnings and Precautions

- Never Share a Humalog, Humalog Mix75/25, or Humalog Mix50/50 KwikPen, Cartridge, Reusable Pen Compatible with Lilly 3 mL Cartridges, or Syringe Between Patients: Humalog KwikPens, cartridges, and reusable pens compatible with Lilly 3 mL cartridges must never be shared between patients, even if the needle is changed. Patients using Humalog vials must never share needles or syringes with another person. Sharing poses a risk for transmission of blood-borne pathogens.
- Dose Adjustment, Monitoring, and Considerations: Closely monitor blood glucose in all patients treated with insulin. Change insulin regimens cautiously. Concomitant oral antidiabetic treatment may need to be adjusted.

The time course of action for Humalog, Humalog Mix75/25, and Humalog Mix50/50 may vary in different individuals or at different times in the same individual and is dependent on many conditions, including the delivery site, local blood supply, or local temperature. Patients who change their level of physical activity or meal plan, or experience illness, emotional disturbances, or other stress may require insulin dose adjustment.

Humalog differs from regular human insulin by its rapid onset of action and shorter duration of activity. Humalog should be given within 15 minutes before or immediately after a meal. Humalog Mix75/25 and Humalog Mix50/50 are intended only for subcutaneous administration and should be given within 15 minutes before a meal.

• Hypoglycemia: Hypoglycemia is the most common adverse effect of Humalog, Humalog Mix75/25, and Humalog Mix50/50. The risk of hypoglycemia increases with tighter glycemic control. Educate patients to recognize and manage hypoglycemia. Hypoglycemia can happen suddenly and symptoms may vary for each person and may change over time. Early warning symptoms of hypoglycemia may be different or less pronounced under conditions such as long-standing diabetes, diabetic nerve disease, use of medications such as beta-blockers, or intensified diabetes control. These situations may result in severe hypoglycemia and possibly loss of consciousness prior to the patient's awareness of hypoglycemia. Severe hypoglycemia may be life threatening and can cause seizures or death.

Use caution in patients with hypoglycemia unawareness and who may be predisposed to hypoglycemia. The patient's ability to concentrate and react may be impaired as a result of hypoglycemia. Rapid changes in serum glucose levels may induce symptoms similar to hypoglycemia in persons with diabetes, regardless of the glucose value.

The timing of hypoglycemia usually reflects the time-action profile of the administered insulins. Other factors such as changes in food intake, injection site, exercise, and concomitant medications may also alter the risk of hypoglycemia.

- Allergic Reactions: Severe, life-threatening, generalized allergy, including anaphylaxis, can occur with Humalog, Humalog Mix75/25, and Humalog Mix50/50.
- Hypokalemia: Humalog, Humalog Mix75/25, and Humalog Mix50/50 can cause hypokalemia, which, if untreated, may

Important Safety Information for Humalog, Humalog Mix75/25, and Humalog Mix50/50, continued

Warnings and Precautions, continued

result in respiratory paralysis, ventricular arrhythmia, and death. Use caution in patients who may be at risk for hypokalemia (eg, patients using potassium-lowering medications or medications sensitive to serum potassium concentrations).

- Renal or Hepatic Impairment: Frequent glucose monitoring and insulin dose reduction may be required in patients with renal or hepatic impairment.
- Mixing of Insulins: Patients should be advised NOT to mix Humalog Mix75/25 or Humalog Mix50/50 with any other insulin. Humalog for subcutaneous injection should not be mixed with insulins other than NPH insulin. If Humalog is mixed with NPH insulin, Humalog should be drawn into the syringe first. Injection should occur immediately after mixing.
- Humalog Use in a Subcutaneous Insulin Infusion Pump: Humalog should not be diluted or mixed when used in an external insulin pump. Change Humalog in the reservoir at least every 7 days. Change the infusion set and insertion site at least every 3 days. Malfunction of the insulin pump or infusion set or insulin degradation can rapidly lead to hyperglycemia and ketosis. Prompt correction of the cause of hyperglycemia or ketosis is necessary. Interim subcutaneous injections with Humalog may be required. Train patients using an insulin pump to administer insulin by injection and to have alternate insulin therapy available in case of pump failure.
- Humalog Mix75/25 and Humalog Mix50/50 should never be used in a pump.
- **Drug Interactions:** Some medications may alter glucose metabolism, insulin requirements, and the risk for hypoglycemia or hyperglycemia. The signs of hypoglycemia may be reduced or absent in patients taking anti-adrenergic drugs. Particularly close monitoring may be required.
- Fluid Retention and Heart Failure with Concomitant Use of PPAR-gamma Agonists: Thiazolidinediones (TZDs), which are PPAR-gamma agonists, can cause dose-related fluid retention, particularly when used in combination with insulin, including Humalog, Humalog Mix75/25, or Humalog Mix50/50. Fluid retention may lead to or exacerbate heart failure. Observe patients for signs and symptoms of heart failure and consider discontinuation or dose reduction of the PPAR-gamma agonist.

Adverse Reactions

 Adverse reactions associated with Humalog, Humalog Mix75/25, and Humalog Mix50/50 include hypoglycemia, hypokalemia, allergic reactions, injection-site reactions, lipodystrophy, pruritus, rash, weight gain, and peripheral edema.

Use in Specific Populations

• Pediatrics: Humalog has not been studied in children with type 1 diabetes less than 3 years of age or in children with type 2 diabetes. Safety and effectiveness of Humalog Mix75/25 and Humalog Mix50/50 in patients less than 18 years of age have not been established.

Please see accompanying Full Prescribing Information.

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