HUMALOG®
MIDODREL INJECTION (U-100)

GROUP SUMMARY: Consult package insert for complete prescribing information.

PRECAUTIONS AND USAGE: Humalog is an insulin analog that is indicated in the treatment of patients with diabetes mellitus for the control of hyperglycemia as an adjunct to diet and exercise. Humalog, administered in an insulin pump, has not been studied in patients with type 2 diabetes.

CONTRAINDICATIONS: Humalog is contraindicated during episodes of hypoglycemia and in patients sensitive to human insulin.

WARNING: This human insulin analog differs from regular human insulin by the rapid onset of action as well as by the nature of its pharmacological actions. The effects on blood glucose are less pronounced than with regular human insulin.

PRECAUTIONS: Consult package insert for complete prescribing information.

Hypoglycemia: As with all insulin preparations, hypoglycemic reactions may be associated with the use of Humalog. Early symptoms may include shakiness, nausea,出汗, irritability, confusion, hunger, or rapid heartbeat. Later symptoms may include dizziness, cold sweats, weakness, or unconsciousness. Hypoglycemia may be less pronounced under certain conditions, such as during vigorous exercise, conditions of stress, or in elderly or alcoholic patients. Elderly patients are more susceptible to the prolonged hypoglycemic episodes that can occur with insulin treatment. Elderly patients, especially those with inadequate insulin therapy, may not manifest the usual symptoms of hypoglycemia. These patients may experience an agitated state, autonomic instability, or altered states of consciousness. Laboratory tests, including serum glucose, ketones, and electrolytes, may be helpful in evaluating patients with hypoglycemia.

Systemic Allergy: At-risk patients should receive an intramuscular test dose of Humalog to determine the absence of systemic allergy before first use. Any allergic reaction, including local reactions, should not preclude the administration of Humalog. If a systemic reaction occurs, Humalog should be withheld and patients should be immediately treated until symptoms resolve.

Use in an External Insulin Pump: Humalog should be used only in an insulin pump with the appropriate pump interface and delivery system for Humalog. Patients should be trained in the use of their pump. If the pump is removed during the course of therapy, the appropriate insulin delivery system should be immediately replaced to ensure adequate insulin delivery.

Use in an External Insulin Pump: Humalog should be used with an insulin pump only. Humalog should not be diluted or mixed with any other insulin when used in an external insulin pump.

Laboratory Tests: As with all insulin preparations, glucose-lowering effect, as measured by HbA1c, was achieved regardless of treatment group: regular human insulin 30 to 50 mmol/L, Humalog 50 to 80 mmol/L. Dilation of dosage of any insulin may be necessary if patients change their physical activity or their usual dose of insulin.

Drug Interactions: Drug interactions with Humalog have not been studied in detail. For information on drug interactions with other insulin preparations, see the package insert for the insulins used in combination with Humalog.

Elderly Patients: Elderly patients are more susceptible to the prolonged hypoglycemic episodes that can occur with insulin treatment. Elderly patients, especially those with inadequate insulin therapy, may not manifest the usual symptoms of hypoglycemia. These patients may experience an agitated state, autonomic instability, or altered states of consciousness. Laboratory tests, including serum glucose, ketones, and electrolytes, may be helpful in evaluating patients with hypoglycemia.

Lactation: It is not known whether humalog is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Humalog is administered to a nursing woman.

Other: Use in patients with renal impairment: The pharmacokinetics of Humalog have been evaluated in patients with varying degrees of renal function (see CLINICAL PHARMACOLOGY). Use in patients with liver impairment: The pharmacokinetics of Humalog have been evaluated in patients with varying degrees of hepatic function (see CLINICAL PHARMACOLOGY).

Drug Metabolism: Concerns have been raised regarding the metabolism of that portion of Humalog (acting within 5 minutes of injection) that is not immediately absorbed into the systemic circulation. These concerns are related to metabolism by degrading or splitting enzymes. These enzymes are produced by the body and are involved in the breakdown of proteins, lipids, and carbohydrates. The metabolism of Humalog by these enzymes can result in the formation of small protein fragments, which can be excreted in the urine.

Nursing Mothers: Humalog should not be used by women who are pregnant or plan to become pregnant. Humalog is a category B pregnancy drug. Nursing mothers who are not pregnant should use Humalog only if the potential benefit justifies the potential risk to the fetus. Women who are pregnant may use Humalog if the benefit justifies the potential risk to the fetus. Women who are pregnant or plan to become pregnant should not use Humalog.

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