Mypart

Injection

DRUG INTERNATIONAL LTD.

Composition: Mypart: Each ml solution contains Insulin Aspart (rDNA) USP 100IU (Eqv. to 3.5mg).

Description: Insulin Aspart is a rapid-acting human insulin analog used to lower blood glucose. Insulin Aspart is homologous with regular human insulin with the exception of a single substitution of the amino acid proline by aspartic acid in position B28, and is produced by recombinant DNA technology utilizing *Saccharomyces cerevisiae* (baker's yeast).

The primary activity of insulin, including Insulin Aspart is the regulation of glucose metabolism. Insulin, and its analogs lower blood glucose by stimulating peripheral glucose uptake, especially by skeletal muscle and fat, and by inhibiting hepatic glucose production. Insulin inhibits lipolysis and proteolysis, and enhances protein synthesis.

Indications: Insulin Aspart is indicated to improve glycemic control in adults and children with diabetes mellitus.

Instructions to be given to the patient

1. Wash your hands with soap and water.

2. Before you start to prepare your injection, check the Mypart label to make sure that you are taking the right type of insulin. This is especially important if you use more than 1 type of insulin.

3. Mypart should look clear and colorless. Do not use Mypart if it is thick, cloudy, or is colored.

4. Do not use Mypart past the expiration date printed on the label.

Dosage:

Subcutaneous Injection

Insulin Aspart should be administered by subcutaneous injection in the abdominal region, buttocks, thigh, or upper arm. Because Insulin Aspart has a more rapid onset and a shorter duration of activity than human regular insulin, it should be injected immediately (within 5-10 minutes) before a meal. Blood glucose monitoring is essential in all patients with diabetes. Patients who change their level of physical activity or meal plan may require adjustment of insulin dosage.

Injection sites should be rotated within the same region from one injection to the next to reduce the risk of lipodystrophy.

Intravenous Use

Insulin Aspart can be administered intravenously under medical supervision for glycemic control with close monitoring of blood glucose and potassium levels to avoid hypoglycemia and hypokalemia. For intravenous use, Insulin Aspart should be used at concentrations from 0.05 U/ml to 1.0 U/ml Insulin Aspart in infusion systems using polypropylene infusion bags. Insulin Aspart has been shown to be stable in infusion fluids such as 0.9% sodium chloride. Inspect Insulin Aspart for particulate matter and discoloration prior to parenteral administration. Or, as directed by the registered physician.

Side Effects: Most common side effects are hypoglycemia, allergic reactions, injection site reactions, lipodystrophy, pruritus and rash.

Contraindications: Insulin Aspart is contraindicated during episodes of hypoglycemia, in patients with hypersensitivity to Insulin Aspart or one of its excipients.

Use in Pregnancy and Lactation: Pregnancy: Pregnancy category B. Careful monitoring of glucose control is essential in pregnant patients because insulin requirements change during different stages of pregnany. Therefore, female patients should be advised to tell their physician if they intend to become or if they become pregnant while taking Insulin Aspart.

Lactation: it is unknown whether Insulin Aspart is excreted in human milk. Use of Insulin Aspart is compatible with breastfeeding, but women with diabetes who are lactating may require adjustments of their insulin doses.

Precautions: Dose adjustment and monitoring: Blood glucose should be monitored in all patients treated with insulin. Insulin regimens should be modified cautiously and only under medical supervision.

Renal and Hepatic Impairment: Reduction in the Insulin Aspart dose may require in these cases.

Drug Interactions: A number of drugs affect glucose metabolism and may require dose adjustment.

The following substances may reduce the insulin as well as Insulin Aspart requirements: oral anti-diabetic products, pramlintide, angiotensin converting enzyme (ACE) inhibitors, disopyramide, fibrates, fluoxetine, monoamine oxidase inhibitors, propoxyphene, pentoxifylline, salicylates, somatostatin analog and sulfonamide antibiotics.

The following substances may increase the insulin as well as Insulin Aspart requirements: corticosteroids, niacin, danazol, diuretics, hormones, sympathomimetic agents, isoniazid, phenothiazine derivatives, somatropin, thyroid hormones, estrogen, progestogens, atypical antipsychotics.

Beta-blockers, clonidine, lithium salts, and alcohol may either potentiate or weaken the blood glucose lowering effect of insulin.

Overdose: Excess insulin administration may cause hypoglycemia and,particularly when given intravenously, hypokalemia. Mild episodes of hypoglycemia usually can be treated with oral glucose. Adjustments in drug dosage, meal patterns, or exercise may be needed. Hypokalemia must be corrected appropriately.

Storage: Store unopened vial at 2^{O} C to 8^{O} C in the refrigerator. Do not freeze. In case of insulin for recent use need not be refrigerated, try to keep it in cool place and keep away from heat and light. The insulin in use can be kept under the room temperature for 4 weeks.

Packing: Mypart: Each box contains 1x3ml vial.