

Composition: Mypart Mix Penset: Each ml suspension contains Insulin Aspart (rDNA) BP 100 IU (equivalent to 3.5 mg) as 30% Soluble Insulin Aspart & 70% Insulin Aspart Protamine.

Description: Mypart Mix (Insulin Aspart & Insulin Aspart Protamine) is a human insulin analog suspension containing 30% Insulin Aspart & 70% Insulin Aspart Protamine 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: Mypart Mix is a mixture of Insulin Aspart and Insulin Aspart Protamine indicated to improve glycemic control in patients with diabetes mellitus.

Instructions to be given to the patient

Cartridge:

Before injecting this Insulin:

1. Always check insulin labels before administration to make sure it is the right type of insulin.
2. Inject Mypart Mix subcutaneously in the abdominal region, buttocks, thigh, or upper arm.
3. Administer the dose within 15 minutes before meal initiation. For patients with type 2 diabetes, the dose may also be given after meal initiation.
4. Rotate injection sites within the same region from one injection to the next to reduce the risk of lipodystrophy.
5. According to the instruction given with MyPen, insert the Mypart Mix cartridge into the pen correctly & equip the needle.
6. Roll the cartridge between your palms 10 times- it is important that the cartridge is kept horizontal (level with the ground). Move the cartridge up and down 10 times so that the glass ball moves from one end of the cartridge to the other.
7. Repeat the rolling and moving procedures until the liquid appears uniformly white and cloudy. Do not use the cartridge if the resuspended insulin does not look uniformly white and cloudy.
8. Mypart Mix must be resuspended immediately before use. Resuspension is easier when the insulin has reached room temperature.
9. Remove the needle cap, discharge air bubbles in the cartridge.
10. Adjust the dosage button to get correct dose & inject to the specific site.
11. Always use a new needle for each injection to prevent contamination.
12. Do not administer Mypart Mix intravenously or use in insulin infusion pumps.
13. Do not use Mypart Mix past the expiration date printed on the label.
14. Do not mix Mypart Mix with any other insulins.
15. Complete the other stages of injection without delay.

For detail description, please see the Patient Instruction Leaflet provided with MyPen.

Resuspension:

Check that there are at least 12 units of insulin left in the cartridge to allow even resuspension. If there are less than 12 units left, use a new cartridge.

Dosage:

- Mypart Mix is typically dosed twice-daily (with each dose intended to cover 2 meals or a meal and a snack).
- Individualize and adjust the dosage of Mypart Mix based on the individual's metabolic needs, blood glucose monitoring results and glycemic control goal.

Mypart Mix

Insulin Aspart Protamine
(rDNA) BP Injection



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- Dosage adjustments may be needed with changes in physical activity, changes in meal patterns, changes in renal or hepatic function or during acute illness.

- Dosage adjustment may be needed when switching from another insulin to Mypart Mix.

Or, as directed by the registered physician.

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

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

Use in Pregnancy and Lactation: Pregnancy: Pregnancy category B. There are no available data in pregnant women to inform a drug-associated risk. There are risks to the mother and fetus associated with poorly controlled diabetes in pregnancy.

Lactation: There are no data on the presence of Insulin in human milk, the effect on the breastfed infants, or the effect on the milk production.

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 requirements: anti-diabetic agents, ACE inhibitors, angiotensin II receptor blocking agents, disopyramide, fibrates, fluoxetine, monoamine oxidase inhibitors, pentoxifylline, pramlintide, propoxyphene, salicylates, somatostatin analog and sulfonamide antibiotics.

The following substances may increase the insulin requirements: atypical antipsychotics, corticosteroids, danazol, diuretics, estrogen, glucagon, isoniazid, niacin, oral contraceptives, phenothiazine, progestogens, protease inhibitors, somatropin, sympathomimetic agents and thyroid hormones.

Beta-blockers, clonidine, lithium salts, alcohol and pentamidine may either potentiate or weaken the blood glucose lowering effect of insulin. Beta-blockers, clonidine, guanethidine and reserpine may blunt the signs and symptoms of hypoglycemia.

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: Storage when not in use: Store in a refrigerator (2° C to 8° C). Do not freeze. After removing Mypart Mix from the refrigerator, it is recommended to allow Mypart Mix to reach room temperature before resuspending the insulin for the first time use.

Storage during use: Mypart Mix that is being used is not kept in the refrigerator. It can be kept at room temperature (below 30° C) for up to 4 weeks. Keep the cartridge in the outer carton in order to protect from light. Mypart Mix must be protected from excessive heat and light.

Packing: Mypart Mix Penset: Each box contains 3x3ml glass cartridges.