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

Description: Insulin Aspart (rDNA) is a sterile, clear solution of Insulin Aspart human insulin analogue for subcutaneous injection/infusion or intravenous injection. Insulin Aspart is a blood glucose lowering agent with an earlier onset of action. Insulin Aspart produces a more rapid onset of action compared to soluble human insulin. 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.

Indications: Insulin Aspart is an insulin analogue indicated to improve glycemic control in patients with diabetes mellitus.

Instructions to be given to the patient

Cartridge:

Before injecting this insulin:

1. Inspect Mypart visually before use. It should appear clear and colorless. Do not use Mypart if particulate matter or coloration is seen.
2. According to the instruction given with MyPen, insert the Mypart cartridge into the pen correctly &
equip the needle.
3. In case of Mypart Mix, gently turn the pen upside down for 8-10 times until the insulin in the cartridge becomes uniformly mixed suspension.
4. Remove the needle cap, discharge air bubbles in the cartridge.
5. Adjust the dosage button to get correct dose & inject to the specific site.
6. In order to avoid cross contamination, do not let the needle touch anything during the process of
preparation.

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

Dosage and administration: Insulin Aspart has a faster onset and a shorter duration of action than soluble human insulin. Due to the faster onset of action, Insulin Aspart should generally be given immediately before a meal. When necessary Insulin Aspart may be given soon after a meal.

Dosage of Insulin Aspart is individual and determined on the basis of the physician's advice in accordance with the needs of the patient. It should normally be used in combination with long-acting insulin given at least once a day.

The individual insulin requirement is usually between 0.5 and 1.0 IU/kg/day in adults and children over 2 years of age. In a meal-related treatment 50-70% of this requirement may be provided by Insulin Aspart and the remainder by long-acting insulin. Adjustment of dosage may also be necessary if patients undertake increased physical activity or change their usual diet. Exercise taken immediately after a meal may increase the risk of hypoglycaemia.

Subcutaneous Injection

Insulin Aspart should be administered by subcutaneous injection in the abdominal region, buttocks, thigh, or upper arm. Injection sites should be rotated within the same region from one injection to the next to reduce the risk of lipodystrophy. 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.

Continuous Subcutaneous Insulin Infusion (CSII) by External Pump

Insulin Aspart can also be infused subcutaneously by an external insulin pump. The initial programming of the external insulin infusion pump should be based on the total daily insulin dose of the previous regimen. Approximately 50% of the total dose is usually given as meal-related boluses of Insulin Aspart and the remainder is given as a basal infusion. When used with an infusion pump Insulin Aspart should not be mixed with any other insulin.

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 hypoglycaemia and

Mypart Penset
Injection

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hypokalaemia. For intravenous use, Insulin Aspart should be used at concentrations from 0.05 IU/ml to 1.0 IU/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. Or, as directed by the registered physician.

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

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

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, angiotensin converting enzyme (ACE) inhibitors, disopyramide, fibrates, fluoxetine, monoamine oxidase inhibitors, propoxyphene, pentoxifylline, salicylates and sulfonamide antibiotics.

The following substances may increase the insulin as well as Insulin Aspart requirements: Thiazides, glucocorticoids, thyroid hormones, beta-sympathomimetics, growth hormone and danazol.

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

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.

Use in pregnancy and lactation: Pregnancy: Pregnancy category B.

Lactation: There are no restrictions on treatment with Insulin Aspart during lactation. Insulin treatment of the nursing mother should not affect the baby. However, dosage may need to be adjusted.

Overdose: A specific overdose for insulin cannot be defined, however, hypoglycaemia may develop over sequential stages if too high doses relative to the patient's requirement are administered.

Mild hypoglycaemic episodes can be treated by oral administration of glucose or sugary products. Severe hypoglycaemic episodes, where the patient has become unconscious, can be treated by glucagon (0.5 to 1 mg) given intramuscularly or subcutaneously. Glucose must also be given intravenously if the patient does not respond to glucagon within 10 to 15 minutes.

Upon regaining consciousness administration of oral carbohydrate is recommended for the patient in order to prevent relapse.

Storage: Do not freeze. Do not use Mypart cartridge if it has been frozen. Keep away from heat and light. Store the cartridge without the needle attached.

Before use: Store unused cartridges at 2° C to 8° C. Unused cartridges may be used until the expiration date printed on the label, if kept in the refrigerator.

If stored outside of refrigeration prior to first use, it should be used within 4 weeks or thrown away.

In-use: Store cartridge you are currently using in the insulin delivery device at room temperature below 30° C for up to 4 weeks. Do not refrigerate. The cartridge you are using should be thrown away after 4 weeks, even if it still has insulin left in it.

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