Glyset™ R

Insulin Aspart (rDNA)

Presentation
Glyset™ R 100 IU: Each ml solution contains 100 IU (equivalent to 3.50 mg) Insulin Aspart (rDNA) BP.

Description
Glyset R (Insulin Aspart rDNA) is a sterile, clear solution of Insulin Aspart human insulin analogue for subcutaneous injection/infusion or intravenous injection. Glyset R is a blood glucose lowering agent with an earlier onset of action. Glyset R 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.

Indication and uses
Glyset R is an insulin analog indicated to improve glycemic control in patients with diabetes mellitus.

Instructions to be given to the patient
Before injecting this Insulin:
1. Disinfect the rubber stopper.
2. If suspension, roll the vial between the palms of the hands until the liquid is uniformly white and cloudy.
3. Draw into the syringe the same amount of air as the dose of insulin to be injected.
4. Inject the air into the vial.
5. Turn the vial and syringe upside down and draw the correct insulin dose into the syringe. Withdraw the needle from vial and expel the air from the syringe and check that the dose is correct.
6. Inject immediately.

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

Dosage of Glyset R 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 Glyset R 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
Glyset R should be administered by subcutaneous injection in the abdominal region, buttocks, thigh, or upper arm. Because Glyset R 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
Glyset R 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 Glyset R and the remainder is given as a basal infusion. When used with an infusion pump Glyset R should not be mixed with any other insulin.

Intravenous Use
Glyset R 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, Glyset R should be used at concentrations from 0.05 IU/mL to 1.0 IU/mL insulin aspart in infusion systems using polypropylene infusion bags. Glyset R has been shown to be stable in infusion fluids such as 0.9% sodium chloride.

Side-effects
Side effects of Insulin Aspart are hypoglycemia, allergic reactions, injection site reaction, lipodystrophy, pruritus and rash.

Use in pregnancy and lactation
Pregnancy: Pregnancy category B.
Lactation: There are no restrictions on treatment with Glyset R during lactation. Insulin treatment of the nursing mother should not affect the baby. However, dosage may need to be adjusted.

Precaution
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

Contraindications
• Hypoglycaemia
• Hypersensitivity to insulin aspart or any of the excipients

Drug interaction
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.

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
Store at 2 °C to 8 °C in a refrigerator. Do not freeze. Protect from light.

Commercial Pack
Glyset™ R 100 IU: Each box contains 1 glass vial of 3 ml Insulin Aspart. Each ml solution contains 100 IU (equivalent to 3.50 mg) Insulin Aspart (rDNA) BP.

Manufactured by
Incepta Pharmaceuticals Ltd
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