Glyset™ Vita

Insulin Aspart (rDNA)

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

Description
Glyset™ Vita (Insulin Aspart rDNA) is a sterile, clear solution of insulin aspart an insulin analogue for subcutaneous injection/infusion or intravenous injection which is produced by recombinant DNA technology. Glyset™ Vita is a blood glucose lowering agent with an earlier onset of action. Glyset™ Vita produces a more rapid onset of action compared to soluble human insulin. Glyset™ Vita is a mealtime Insulin Aspart formulation which 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 addition of nicotinamide (Vitamin B3) results in a faster initial absorption of insulin and appeared in the circulation approximately 4 minutes after administration.

Indications
Glyset™ Vita is an insulin analog indicated for the treatment of diabetes mellitus in adults, adolescents and children aged 1 year and above.

Dosage and administration
Glyset™ Vita has a faster onset and a shorter duration of action than soluble human insulin. Due to the faster onset of action, inject at the start of a meal or within 20 minutes after starting a meal.

Dosage of Glyset™ Vita 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 U/kg/day in adults, adolescent and children. In a meal-related treatment 50-70% of this requirement may be provided by Glyset™ Vita 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.

Patients with type 1 diabetes: As a general rule 0.2 to 0.4 units of insulin per kg of body weight can be used to calculate the initial total daily insulin dose for type 1 diabetes.

Patient with type 2 diabetes: The suggested initial dose is 4 units at one or more meals. The number of injections and subsequent titration will depend on the individual glycemic target and the size and composition of the meals.

Dose Adjustment: Dose adjustment may be considered daily based on self- measured plasma glucose (SMPG) on the previous day.

SMPG (Self Measured Plasma Glucose)		Glyset Vita dose adjustment
mmol/l	mg/dl	Unit
< 4.0	<71	-1
4.0-6.0	71-108	No adjustment
>6.0	>108	+1

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

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

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.

Drug interaction
A number of drugs affect glucose metabolism and may require dose adjustment of Insulin aspart.

The following substances may reduce the Insulin aspart requirements:
Oral anti-diabetic products, monoamine oxidase inhibitors, beta-blockers, angiotensin converting enzyme (ACE) inhibitors, salicylates, anabolic steroids, sulfonamide and GLP-1 receptor agonist.

The following substances may increase the Insulin aspart requirements:
Oral contraceptives, thiazides, glucocorticoids, thyroid hormones, sympathomimetics, growth hormone and danazol.

Beta-blockers may mask the symptoms of hypoglycemia.

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 ºC to 8 ºC. After first opening, do not refrigerate again. Protect from light. Do not freeze. Keep out of the reach of children.

Commercial Pack:
Glyset™ Vita Vial 100 IU: Each box contains 1 vial of 3 ml insulin Aspart Injection.
Glyset™ Vita PenSet 100 IU: Each box contains blister strip of 1 cartridge of 3 ml insulin Aspart Injection.

Manufactured by
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