For the use only of a Registered Medical Practitioner or Hospital or a Laboratory

Abridged Prescribing Information

INSULIN GLULISINE INJECTION (r-DNA origin)
APIDRA® 100IU/mL

COMPOSITION
1 ml contains 3.5 mg insulin glulisine, corresponding to 100 IU human insulin.
Each cartridge and pre-filled disposable pen (SoloStar®) contains 3 ml, equivalent to 300 IU insulin. Each vial contains 10 ml equivalent to 1000 IU.

THERAPEUTIC INDICATIONS
Treatment of adults, adolescents and children of 6 years or older with diabetes mellitus, where treatment with insulin is required.

DOSAGE & ADMINISTRATION
The dosage of Apidra® should be individually adjusted. Apidra® should normally be used in regimens that include a longer-acting insulin or basal insulin analogue. Blood glucose monitoring is recommended for all patients with diabetes. Apidra® should be given by subcutaneous injection within 15 minutes before a meal or within 20 minutes after starting a meal. Apidra® is intended for subcutaneous administration by injection or by external infusion pump. Apidra® can also be administered intravenously. There is insufficient clinical information on the use of Apidra® in children younger than the age of 6 years. Hypoglycaemia may be difficult to recognize in the elderly.

SAFETY-RELATED INFORMATION
CONTRAINDICATIONS: Hypersensitivity to insulin glulisine or to any of the excipients.

WARNINGS & PRECAUTIONS: Patients with diabetes will also require a longer-acting insulin or insulin infusion pump therapy to maintain adequate glucose control. Any change of insulin should be made cautiously and only under medical supervision. Changes in insulin strength, manufacturer, type, species or method of manufacture may result in the need for a change in dosage. Concomitant oral antidiabetic treatment may need to be adjusted. Insulin requirements may be altered during intercurrent conditions such as illness, emotional disturbances, or stress. Patients must be instructed to perform continuous rotation of the injection site to reduce the risk of developing lipodystrophy and localized cutaneous amyloidosis. There is a potential risk of delayed insulin absorption and worsened glycemic control following insulin injections at sites with these reactions. A sudden change in the injection site to an unaffected area has been reported to result in hypoglycemia. Blood glucose monitoring is recommended after the change in the injection site, and dose adjustment of antidiabetic medications may be considered. The time of occurrence of hypoglycaemia depends on the action profile of the insulins used and may, therefore, change when the treatment regimen is changed. Apidra® requirement may be reduced in renal and hepatic impairment. Apidra® cartridges should be used with Allstar® and not with any other reusable pen as dosing accuracy has only been established with Allstar® Patients using continuous subcutaneous insulin infusion pump therapy must be trained to administer insulin by injection and have alternate insulin delivery system available. For intravenous use, Apidra® should be used at a concentration of 1 unit/mL insulin glulisine in infusion systems with the infusion fluid sterile 0.9% sodium chloride solution. Apidra® was found to be incompatible with Dextrose solution and Ringer's solution and, therefore, can not be used with these solution fluids.

PREGNANCY AND LACTATION: No adequate data are available. Insulin requirements may decrease during the first trimester and generally increase during the second and third trimesters and decline after delivery**.** It is unknown whether Apidra® is excreted in human milk. Lactating women may require dose and diet adjustment.

ADVERSE REACTIONS: Hypoglycemia is the most frequent undesirable effect of insulin therapy. Injection site reactions and local hypersensitivity reactions may occur. Severe cases of generalised allergy, including anaphylactic reaction, may be life-threatening. Lipodystrophy may occur at the injection site. Localized cutaneous amyloidosis at the injection site has occurred with insulins. Hyperglycemia has been reported with repeated insulin injections into areas of localized cutaneous amyloidosis; hypoglycemia has been reported with a sudden change to an unaffected injection site. Medication errors have been reported in which other insulins, particularly long-acting insulins, have been accidentally administered instead of insulin glulisine.

For full prescribing information please write to Sanofi India Ltd., Sanofi House, CT Survey No 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai 400072

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