Prescribing Information

Apidra® (insulin glulisine). Please refer to Summary of Product Characteristics prior to use of Apidra. Apidra cartridges and Solostar prefilled pens each contain 300 Units of insulin glulisine in 3ml, equivalent to 10.47mg. Apidra vials contain 1000 Units insulin glulisine in 10ml, equivalent to 34.9mg. **Indications:** Treatment of diabetes mellitus in adults, adolescents and children of 6 years or above. **Dosage and administration:** Intravenous: Apidra can be administered intravenously by health care professionals. Apidra must not be mixed with glucose or Ringer's solution or with any other insulin. Subcutaneous: Apidra can be given subcutaneously shortly (0-15 min) before or soon after meals or by continuous subcutaneous pump infusion. When administered as a subcutaneous injection, Apidra must not be mixed with other medicinal products except NPH human insulin. When used with a subcutaneous insulin infusion pump, Apidra must not be mixed with diluents or any other insulin. Patients must follow the Apidra specific instructions in the SPC when using Apidra in a pump. Failure to do so may lead to serious adverse events. Apidra should be used with an intermediate or long acting insulin or basal insulin analogue and can be used with oral hypoglycaemic agents. The dosage of Apidra should be individually adjusted. There is insufficient clinical information on the use of Apidra in children under 6 years. The pharmacokinetic properties of insulin glulisine are generally maintained in patients with renal impairment. Insulin requirements may be diminished in the elderly or patients with renal or hepatic impairment. **Contraindications:** Hypersensitivity to insulin glulisine or any excipients. **Precautions and warnings:** Use of inadequate dosages or discontinuation of treatment, especially in insulin-dependent diabetics, may lead to hyperglycaemia and diabetic ketoacidosis; conditions which are potentially lethal. Dosage adjustment may be necessary if patients undertake increased physical activity or change their meal plan. Uncorrected hypoglycaemic or hyperglycaemic reactions can cause loss of consciousness, coma or death. Cases of cardiac failure have been reported when pioglitazone was used in combination with insulin, especially in patients with risk factors for development of cardiac heart failure. Patients on this combination should be observed for signs and symptoms of heart failure, weight gain and oedema. When administered by continuous subcutaneous infusion, malfunction of the insulin pump or infusion set or handling errors can rapidly lead to hyperglycaemia, ketosis and diabetic ketoacidosis. Patients using continuous subcutaneous insulin infusion pump therapy must have an alternative insulin delivery system available in case of pump failure. Pioglitazone should be discontinued if any deterioration in cardiac symptoms occurs. **Pregnancy and lactation:** There are no adequate data on the use of insulin glulisine in pregnant women therefore caution should be exercised. It is unknown if insulin glulisine is excreted in breast milk. **Adverse reactions:** Very common: hypoglycaemia. Hypoglycaemia can become severe and may lead to unconsciousness and/or convulsions and may result in temporary or permanent impairment of brain function or even death. Common: injection site reactions and local hypersensitivity reactions, which are usually transitory and normally disappear during continued treatment. Uncommon: Systemic hypersensitivity reactions, which may include urticaria, chest tightness, dyspnea, allergic dermatitis and pruritus. Severe cases of generalized allergy, including anaphylactic reaction, may be life-threatening. Rare: lipodystrophy. Unknown; Hyperglycaemia (potentially leading to Diabetic ketoacidosis - Most of these cases were related to handling errors or pump system failure when Apidra was used with CSII). Please consult Summary of Product Characteristics for full details of the recognised side effects with Apidra. **NHS price:** 1 x 10ml vial £16.00; 5 x 3ml cartridge £28.30; 5 x 3ml SoloStar £28.30. **Legal category:** POM. **MA holder**: Sanofi Aventis Deutschland GmbH, D-65926 Frankfurt am Main, Germany. **MA Numbers:** Apidra vial: EU/1/04/285/001; Apidra cartridge: EU/1/04/285/008; Apidra SoloStar:

EU/1/04/285/032. **Full prescribing information is available from:** Sanofi, One Onslow Street, Guildford, Surrey, GU1 4YS. Tel: 01483 505515. **Date of Revision:** December 2013

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.
Adverse events should also be reported to the Sanofi drug safety department on 01483 505515.