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 10.9mg. 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 used in the care of people with a very severe health care professional. 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 dextran or any other insulin. Patients must follow the Apida specific instructions in the SPC when using Apida 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 impairments, and renal impairment may be diminished in the elderly or patients with renal or hepatic impairment.

Contraindications: Hyperinsensitivity 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. Patients 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 result in hyperglycaemia or hypoglycaemia. Ketonuria and ketonotic diabetic ketoacidosis 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 should be observed for signs and symptoms of heart failure, weight gain and oedema.

Lantus® (insulin glargine)

Please refer to Summary of Product Characteristics prior to use of Lantus. Lantus cartridges and Solostar prefilled pens each contain 300 Units of insulin glargine in 3ml, equivalent to 10.92mg. Indications: Treatment of diabetes mellitus in adults, adolescents and children of 2 years or above. Dosage and administration: Lantus is administered subcutaneously once daily, at any time but at the same time each day.

No data are available. Contraindications: Hypersensitivity, to insulin glargine or any excipients. Precautions and warnings: Lantus is not the insulin of choice for treatment of diabetic ketoacidosis. In case of insufficient glucose control or a tendency to hypoglycaemia episodes all relevant factors must be reviewed. Dose adjustment is considered. Particular caution should be exercised, and intensified blood monitoring is advisable for patients in whom hypoglycaemic episodes might be of clinical relevance and in those who dose adjustments may be required. Warning signs of hypoglycaemia may be changed, less pronounced or absent in certain risk groups, potentially resulting in severe hypoglycaemia and loss of consciousness. Risk groups include patients in whom glycaemic control is markedly improved, hypoglycaemia develops gradually, an autonomic neuropathy is present, or in elderly patients. Intensified metabolic monitoring is necessary during intercurrent illness. Failure to have been reported when pioglitazone was used in combination with insulin, especially in patients with risk factors for development of cardiac heart failure. Patients should be observed for signs and symptoms of heart failure, weight gain and oedema.

Legal category: POM. MA holder: Sanofi Aventis Deutschland GmbH, D-69592 Frankfurt am Main, Germany. Full prescribing information is available from: Sanofi, One Osnos Street, Guildford, Surrey, GU4 1YX. Tel: 0845 372 7101. Date of Revision: October 2014

Insulan® (insulin human)

Please refer to Summary of Product Characteristics prior to use of Insulan. Insulan Basal, Comb 15, Comb 25, Comb 50 and Rapid cartridges, in addition to the Insulan Basal and Comb 25 Solostar pens each contain 300 IU of insulin human in 3ml, equivalent to 10.9mg. Insulan Basal and Comb 25 vials contain 500 IU of insulin human in 5ml, equivalent to 17.5mg. Insulan Rapid contains neutral insulin solution (regular insulin). Insulan Basal contains isophane insulin suspension. Insulan Comb 15, 25 and 50 contain 15% regular and 85% isophane, 25% regular and 75% isophane, and 50% regular and 50% isophane insulin, respectively. Indications: Diabetes mellitus. Insulan Rapid cartridges are also suitable for the treatment of hyperinsulinemic hypoglycaemia, and for achieving pre-, intra- and post-operative stabilisation. Dosage and administration: Insulin doses and timings should be determined individually. There are no fixed rules for insulin dosage. Average insulin requirement is often 0.5 to 1.0 IU/kg body weight/day. Basal metabolic requirement is 40% to 60% of total daily requirement. Insulan should be injected subcutaneously. Insulan Rapid should be injected 15 to 20 minutes before a meal. Insulan Basal should be injected 45 to 60 minutes before a meal; Insulan Comb 15 and 25 should be injected 30 to 45 minutes before a meal; Insulan Comb 50 should be injected 20 to 30 minutes before a meal. Insulan Rapid cartridges may also be administered intravenously under close medical supervision. Close metabolic monitoring is recommended during, and for a period after, transition from other insulins to Insulan. Dose and timing of other antidiabetic medicinal products should be adjusted. Dose adjustments may also be required if the patient’s weight or lifestyle changes, the timing of insulin dose is changed or other circumstances arise that increase susceptibility to hypo- or hyperglycaemia. Insulin requirements may be diminished in the elderly or patients with renal or hepatic impairment. Patients on this combination should be observed for signs and symptoms 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 should be observed for signs and symptoms of heart failure, weight gain and oedema.

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of hypoglycaemia). Careful monitoring of glucose control is essential. It is unknown if insulin glargine is excreted in breast milk. There is no experience with Toujeo® in children. Prolonged or severe hypoglycaemia may be life-threatening.

Common: Iphypoglycaemia, injection site reactions, onchitis, eosinophilia, hypertension and shock and may be life threatening; visual impairment, retinopathy and oedema. Very rare: dysgeusia, myalgia Overdose may lead to severe and sometimes long-term and life-threatening hypoglycaemia. Please consult Summary of Product Characteristics for full details of the recognised side effects with Toujeo. NHS price: £33.13 for x 1.5 ml pens.

Legal category: POM. MA holder: sanofi aventis Deutschland GmbH, D-64293 Darmstadt, Germany. MA number(s): Toujeo 10 ml: EU/1/00/133/034. Full prescribing information is available from: Sanofi, One Onslow Street, Guildford, Surrey, GU1 4YS. Tel: 01483 505515 or the Sanofi Diabetes Care Line 08000 35 25 25. Date of Review: May 2015

Toujeo® (insulin glargine 300 U/ml)

Please refer to Summary of Product Characteristics prior to use of Toujeo.

Toujeo Solostar pre-filled pens each contain 450 Units of insulin glargine in 1.5 ml of solution for injection, equivalent to 10.91 mg/ml. Indications: Treatment of diabetes mellitus in patients with type 1 diabetes mellitus, Toujeo must be combined with short-/rapid-acting insulin to cover mealtime insulin requirements. In patients with type 2 diabetes mellitus, Toujeo can also be given together with other anti-hyperglycaemic medicinal products. Close metabolic monitoring is recommended during the switch and in the initial weeks thereafter. Toujeo is not the insulin of choice for treatment of diabetic ketoacidosis. In case of insufficient glucose control or a tendency to hyper/hypoglycaemic episodes, the patient’s adherence to the prescribed treatment regimen, injection sites and proper injection technique and all other relevant factors must be reviewed before dose adjustment is considered. Insulin administration may cause insulin antibodies to form. Rarely, this may necessitate dose adjustment. Particular caution should be exercised, and intensified blood glucose monitoring is advisable for patients in whom hypoglycaemic episodes might be of clinical relevance and in those where dose adjustments may be required. Warning signs of hypoglycaemia may be changed, less pronounced or absent in certain risk groups, potentially resulting in severe hypoglycaemia and loss of consciousness. Risk groups include individuals in whom hypoglycaemia is suspected and improved, hypoglycaemia develops gradually, an autonomic neuropathy is present, or who are elderly. The prolonged effect of subcutaneous insulin glargine may delay recovery from hypoglycaemia. 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. If the combination is used, patients should be observed for signs and symptoms of heart failure, weight gain and oedema. Pioglitazone should be discontinued if any deterioration in cardiac symptoms occurs. Pregnancy and lactation: No clinical data on exposed pregnancies from controlled clinical trials are available. A large amount of data on pregnant women (more than 1000 pregnancy outcomes with a medicinal product containing insulin glargine 100 units/ml (Lantus)) indicate no specific adverse effects on pregnancy and no specific malformative or feto/neonatal toxicity of insulin glargine. Animal data do not indicate reproductive toxicity. The use of Toujeo may be considered during pregnancy, if clinically needed. Insulin requirements may decrease during the first trimester and generally increase during the second and third trimesters. Immediately after delivery, insulin requirements decline rapidly (increased risk of hypoglycaemia). Careful monitoring of glucose control is essential. It is unknown if insulin glargine is excreted in breast milk. Adverse reactions: Very common: Hypoglycaemia. Prolonged or severe hypoglycaemia may be life-threatening. Common: Lipoatrophy. Rare: Immediate-type allergic reactions; which may be associated with generalised skin reactions, angio-oedema, bronchospasm, hypotension and shock and may be life threatening; visual impairment, retinopathy and oedema. Very rare: Dysgeusia, myalgia.

Insulin administration may cause insulin antibodies to form and may, in rare cases, necessitate adjustment of the insulin dose. Overdose may lead to severe and sometimes long-term and life-threatening hypoglycaemia. Please consult Summary of Product Characteristics for full details of the recognised side effects with Toujeo. NHS price: £33.13 for pack of x 1.5 ml pens.

Legal Category: POM. MA Holder: sanofi aventis Deutschland GmbH, D-64293 Darmstadt, Germany. MA number(s): Solostar 3: 3 Pen pack: EU/100/133/034. Full prescribing information is available from: Sanofi, One Onslow Street, Guildford, Surrey, GU1 4YS. Tel: 01483 505515 or the Sanofi Diabetes Care Line 08000 35 25 25. Date of Review: May 2015

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.mhra.gov.uk. Adverse events should also be reported to the Sanofi drug safety department on 01483 554242.