APIDRA® Abbreviated Prescribing Information - Gulf

1. NAME AND PRESENTATION: Apidra 100 U/ml, solution for injection of insuline glulisine is available in vial of 10 ml, cartridge of 3 ml for Optipen & Opticlik, and prefilled pen of 3ml as Optiset & Solostar.

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

3. POSOLOGY AND METHOD OF ADMINISTRATION: Apidra should be given shortly (0-15 min) before or soon after meals and should be used in regimens that include 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. For administration details: see full SmPC. Patients must be educated to use proper injection techniques. Renal impairment & hepatic impairment: insulin requirements may be reduced. Elderly: deterioration of renal function may lead to a decrease in insulin requirements.

4. CONTRA-INDICATIONS: Hypersensitivity to insulin glulisine or to any of the excipients. Hypoglycaemia.

5. SPECIAL WARNINGS AND PRECAUTIONS FOR USE: Transferring a patient to a new type or brand of insulin should be done under strict medical supervision. Changes in strength, brand, type, species and/or method of manufacturing may result in a change in dosage. Concomitant oral antidiabetic treatment may need to be adjusted. Adjustment of dosage may be necessary if patients undertake increased physical activity or change their usual meal plan.

6. DRUG INTERACTIONS: Substances that may enhance or reduce the blood-glucose-lowering activity are detailed in the full SmPC.

7. 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. Breast-feeding mothers may require adjustements in insulin dose and diet.

8. ABILITY TO DRIVE: Patients should be advised to take precautions to avoid hypoglycaemia whilst driving.

9. UNDESIRABLE EFFECTS: Hypoglycaemia is the most frequent undesirable effect of insulin therapy. Injection site reactions and local hypersensitivity reactions. For uncommon & rare adverse events, consult the full SmPC.

10. OVERDOSAGE: Severe hypoglycaemic episodes can be treated by glucagon (0.5 to 1 mg) given intramuscularly or subcutaneously or by glucose given intravenously.

11. PHARMACODYNAMIC PROPERTIES: ATC code: A10AB06.

12. MARKETING AUTHORIZATION HOLDER: Sanofi-Aventis Deutschland GmbH, D 65926 Frankfurt am Main.

Abbreviated Prescribing Information based on the EU SmPC as of April 2018

Last Revised:October 2020

Always refer to the full Summary of Product Characteristics (SmPC) before prescribing