Semglee® (Insulin glargine) 100 units/ml solution for injection in pre filled pen

Prescribing information

Please refer to Summary of Product Characteristics (SmPC) before prescribing.

Indication: Semglee® is indicated in the treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above. Presentation: Each ml contains 100 units insulin glargine* (equivalent to 3.64 mg). Each pen contains 3 ml of solution for injection, equivalent to 300 units. Dosage and administration: Semglee® (insulin glargine) has a prolonged duration of action. It should be administered once daily at any time but at the same time each day. The pre filled pen delivers insulin in increments of 1 unit up to a maximum single dose of 80 units. The dose regimen (dose and timing) should be individually adjusted. In patients with type 2 diabetes mellitus, Semglee® can also be given together with orally active antidiabetic medicinal products. The potency of Semglee® is stated in units and these units are exclusive to Semglee®. Special population: Elderly population (≥ 65 years old): progressive deterioration of renal function may lead to a steady decrease in insulin requirements. Renal impairment: insulin requirements may be diminished due to reduced insulin metabolism. Hepatic impairment: insulin requirements may be diminished due to reduced capacity for gluconeogenesis and reduced insulin metabolism. Paediatric population: For adolescents and children aged 2 years and older patients, the dose regimen (dose and timing) should be individually adjusted. For children below 2 years of age the safety and efficacy of Semglee® have not been established. No data are available. Switch from other insulins to Semglee®: When switching from a treatment regimen with an intermediate or long acting insulin to a regimen with Semglee®, a change of the dose of the basal insulin may be required and the concomitant antidiabetic treatment may need to be adjusted (dose and timing of additional regular insulins or fast acting insulin analogues or the dose of oral antidiabetic medicinal products). Switch from twice daily NPH insulin to Semglee®: To reduce the risk of nocturnal and early morning hypoglycaemia, daily dose of once daily basal insulin should be reduced by 20–30% during the first weeks of treatment. Switch from insulin glargine 300 units/ml to Semglee®: Semglee® and insulin glargine 300 units/ml are not bioequivalent and are not directly interchangeable. To reduce the risk of hypoglycaemia in this group, Semglee® dose should be reduced by approximately 20%. During the first weeks increase mealtime insulin, after this period the regimen should be adjusted individually. Close metabolic monitoring is recommended during the switch and in the initial weeks thereafter. A further adjustment in dose regimen may become necessary with improved metabolic control, change of timing of insulin, patient weight or life style changes. Patients with high insulin doses because of antibodies to human insulin may experience an improved insulin response with Semglee®. Method of administration: Semglee® is administered subcutaneously only. Injection sites must be rotated within a given injection area from one injection to the next. Semglee® must not be mixed with any other insulin or diluted. Before using the pre filled pen, the instructions for use included in the package leaflet must be read carefully. Contraindications: Known hypersensitivity to the active substances or to any of the excipients. Warnings and precautions: Warnings: Semglee® is not the insulin of choice for the treatment of diabetic ketoacidosis. In case of insufficient glucose control or a tendency to hyper or 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. Changes in insulin strength, manufacturer, type, origin, method of manufacture and/or method of administration may result in the need for a change in insulin dose or an adjustment in concomitant oral antidiabetic treatment. Hypoglycaemia: Due to more sustained basal insulin supply with Semglee®, less nocturnal but more early morning hypoglycaemia can be expected. Intercurrent illness: In many cases urine tests for ketones are indicated, and often it is necessary to adjust the insulin dose. The insulin requirement is often increased. Patients with type 1 diabetes must continue to consume at least a small amount of carbohydrates on a regular basis, even if they are able to eat only little or no food or are vomiting etc. and they must never omit insulin entirely. Insulin antibodies: rare chance of antibodies formation, may require insulin dose adjustment to avoid hyper- or hypoglycaemia. Handling of the pen: Before using Semglee® pen, the instructions for use included in the package leaflet must be read carefully. Semglee® pen has to be used as recommended in the instructions for use. Medication errors: Insulin label must always be checked before each injection to avoid medication errors between insulin glargine and other insulins. Interaction with other medicinal products: Pioglitazone should be discontinued if any deterioration in cardiac symptoms occurs when used with Semglee®. Substances that may enhance the blood glucose lowering effect include oral antidiabetic medicinal products, angiotensin converting enzyme (ACE) inhibitors, disopyramide, fribates, fluoxetine, monoamine oxidase (MAO) inhibitors, pentoxifylline, propoxyphene, salicylates and sulfonamide antibiotics. Substances that may reduce the blood glucose lowering effect include corticosteroids, danazol, diazoxide, diuretics, glucagon, isoniazid, oestrogens and progestogens, phenoxyethanol derivatives, somatropin, sympathomimetic medicinal products (e.g. epinephrine [adrenaline], salbutamol, terbutaline), thyroid hormones, atypical antipsychotic medicinal products (e.g. clozapine and olanzapine) and protease inhibitors. Beta blockers, clonidine, lithium salts or alcohol may either potentiate or weaken the blood glucose lowering effect of insulin. Pentamidine may cause hypoglycaemia, which may sometimes be followed by hyperglycaemia. Pregnancy and lactation: Pregnancy For insulin glargine no clinical data on exposed pregnancies from controlled clinical studies are available. A large amount of data on pregnant women (more than 1000 pregnancy outcomes) indicate no specific adverse effects of insulin glargine on pregnancy and no specific malformative nor foeto/neonatal toxicity of insulin glargine. Animal data do not indicate reproductive toxicity. The use of Semglee® may be considered during pregnancy, if clinically needed. Careful monitoring of glucose control is essential. Breast feeding It is unknown whether insulin glargine is excreted in human milk. Women may require adjustments in insulin dose and diet. Effects on ability to drive and use machines: The patient’s ability to concentrate and react may be impaired as a result of hypoglycaemia or hyperglycaemia or, for example, as a result of visual impairment. Undesirable effects: Very common: Hypoglycaemia. Common: Lipohypertrophy, injection site reactions. Uncommon: Lipatrophy. For rare and very rare undesirable effects, please refer to SmPC. Name and Address of Marketing Authorisation Holder: Mylan S.A.S., 117 allée des Parcs, 69800 Saint Priest, France. Marketing Authorisation Number: EU/1/18/1270/003 Basic NHS price: 3ml x 5 pens = £29.99 Legal Category: POM Date of Last Revision: October 2018 Detailed information on this medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu and from Mylan Medical Information, Building 4, Trident Place, Hatfield Business Park, Mosquito Way, Hatfield, Hertfordshire, AL10 9UL, phone no. 01707 853000, Email: info@mylan.co.uk

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare providers are asked to report any suspected adverse reactions. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard In order to support effective tracking and traceability of biologics including biosimilars, it is recommended that the brand name and batch number are recorded and used when reporting adverse events.