PROFESSIONAL INFORMATION

SCHEDULING STATUS S3

1. NAME OF THE MEDICINE:

TOUJEO® solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

1 mL contains 10,91 mg insulin glargine, corresponding to 300 U (units) of insulin glargine.

* Insulin glargine is produced by recombinant DNA technology in *Escherichia coli.*

Preservative: metacresol 0,27 % *m/v.*

Sugar free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM:

Solution for injection.

Colourless to almost colourless solution, clear and practically free from particles in a pre-filled disposable pen with a 1,5 ml cartridge.

4. CLINICAL PARTICULARS:

4.1 Therapeutic indications:

Treatment of diabetes mellitus in adults, adolescents and children from the age of 6 years.

4.2 Posology and method of administration:

Posology:

Insulin glargine 300 U/mL is a long-acting recombinant human insulin analogue product.

These units are exclusive to TOUJEO and are not the same as international units (IU) or the units used to express the potency of other insulin analogues.

TOUJEO is given subcutaneously.

TOUJEO is administered once daily, at any time during the day, preferably at the same time every day.

TOUJEO allows for flexibility in the once-daily time of administration.
When needed, patients can administer their injections up to 3 hours before or after their usual time of administration.

The desired blood glucose levels as well as the doses and timing of anti-hyperglycaemic medicines must be determined and adjusted individually.

Dose adjustment may be required, for example, if the patient's body mass or lifestyle changes, if there is a change in the timing of insulin dose or if other circumstances arise that increase susceptibility to hypo- or hyperglycaemia.

Any change of insulin dose should be made cautiously and only under medical supervision.

TOUJEO should never be used for the treatment of diabetic ketoacidosis.

An intravenous, short-acting insulin is the preferred treatment.

Initiation of TOUJEO:
Patients with type 1 diabetes mellitus: TOUJEO is to be used once-daily with meal-time insulin and requires individual dose adjustments.

Patients with type 2 diabetes mellitus: The recommended daily starting dose is 0,2 U/kg body mass once daily followed by individual dosage adjustments.

Change from other insulins to TOUJEO:

When changing from a treatment regimen with an intermediate-acting or another long-acting insulin to a regimen with TOUJEO , the amount and timing of short-acting insulin or fast-acting insulin analogue or of the dose of any anti-hyperglycaemic medicine may need to be adjusted.

- Changing from once-daily basal insulin to once-daily TOUJEO can be done unit-to-unit based on the previous basal insulin dose
- Changing from twice-daily basal insulin to once-daily TOUJEO , the recommended initial TOUJEO dose is 80 % of the total daily dose of the insulin that is being discontinued.

A programme of close metabolic monitoring under medical supervision is recommended during the change and in the initial weeks thereafter. This is particularly true for patients who, due to antibodies to human insulin, may need high TOUJEO doses.

Change from TOUJEO to basal insulins:

Medical supervision with close metabolic monitoring is recommended during the change and in the initial weeks thereafter.

Refer to the professional information leaflet of the product to which the patient is changing.

Special populations:

TOUJEO can be used in elderly people, patients with renal and hepatic impairment, children and adolescents from the age of 6 years.

Children: TOUJEO can be used in children and adolescents from the age of 6 years (see section 5.1). When switching basal insulin to TOUJEO, dose reduction of basal and bolus insulin needs to be considered on an individual basis, in order to minimise the risk of hypoglycaemia (see section 4.4).

The safety and effectiveness of TOUJEO have not been established in paediatric patients (under 6 years of age). No data are available.

Elderly: TOUJEO can be used in elderly patients.
In elderly patients with diabetes, the initial dosing, dose increments, and maintenance dosage should be conservative to avoid hypoglycaemic reactions. Close glucose monitoring is recommended and the insulin dose should be adjusted on an individual basis.

In the elderly patients, progressive deterioration of renal function may lead to a steady decrease in insulin requirements.

Renal impairment: TOUJEO can be used in patients with renal impairment.
Close glucose monitoring is recommended and the TOUJEO dose should be adjusted on an individual basis.
In patients with renal impairment, insulin requirements may be diminished due to reduced insulin metabolism.

Hepatic impairment: TOUJEO can be used in patients with hepatic impairment.
Close glucose monitoring is recommended and the TOUJEO dose should be adjusted on an individual basis.
In patients with hepatic impairment, insulin requirements may be diminished due to reduced capacity for gluconeogenesis and reduced insulin metabolism.

Method of administration:

TOUJEO is administered by subcutaneous tissue injection.
Injection sites within an injection area (abdomen, thigh and deltoid) must be rotated from one injection to the next to reduce the risk of lipodystrophy and localized cutaneous amyloidosis.

Do not inject into areas of lipodystrophy or localized cutaneous amyloidosis (see sections 4.4 and 4.8).

TOUJEO is not intended for intravenous administration. Intravenous administration of the usual subcutaneous dose could result in severe hypoglycaemia.

TOUJEO is not intended to be administered via an insulin infusion pump.

TOUJEO is a clear solution, not a suspension. As such it does not require re-suspension before use.

With TOUJEO SoloStar pre-filled pen, a dose of 1 – 80 units per injection, in steps of 1 unit, can be injected.

- The dose counter shows the number of TOUJEO units to be injected. The TOUJEO SoloStar pre-filled pen has been specifically designed for TOUJEO, therefore no dose re-calculation is required.
- TOUJEO must never be drawn from the cartridge of the pre-filled pen into a syringe.
- Patients must also be instructed to not re-use needles. A new sterile needle must be attached before each injection. Re-use of needles increases the risk of blocked needles which may cause underdosing or overdosing. Using a new sterile needle for each injection also minimises the risk of contamination and infection.

4.3 Contraindications:

- TOUJEO must not be used in patients hypersensitive to insulin glargine or any of the excipients (see section 6.1).
- Children: The safety and efficacy of TOUJEO have not been established in children below 6 years of age.

4.4 Special warnings and precautions for use:

Hypoglycaemia:

Insulin treatment requires constant alertness to the possibility of hypoglycaemia. Patients and their relatives must know what steps to take if hypoglycaemia occurs or is suspected, and they must know when to inform a doctor.

Patients should be made aware of symptoms of possible hypoglycaemia and should be advised to visit their doctor or an emergency room if they experience these symptoms, including tachycardia, palpitations, dysrhythmia, abnormal perspiration, tremors, drowsiness or any symptoms which may be related to hypoglycaemia.

Caution should be exercised, and intensified blood glucose monitoring is advisable, in patients in whom sequelae of hypoglycaemic episodes might be of particular clinical relevance.

For example, these could be patients with significant stenoses of the coronary arteries or of the blood vessels supplying the brain (risk of cardiac or cerebral complications of hypoglycaemia), as well as patients with proliferative retinopathy, particularly if not treated with photocoagulation (risk of transient amaurosis following hypoglycaemia).

However, under certain conditions, the warning symptoms of hypoglycaemia may be changed, be less pronounced or absent, for example:

- if glycaemic control is markedly improved
- if hypoglycaemia is developing gradually
- in elderly patients
- where an autonomic neuropathy is present

- in patients with a long history of diabetes
- in patients suffering from a psychiatric illness
- in patients receiving concurrent treatment with certain other medicines (see section 4.5).

Such situations may result in severe hypoglycaemia (and possibly, loss of consciousness) prior to the patient's awareness of hypoglycaemia. Severe hypoglycaemic attacks, especially if recurrent, may lead to neurological damage. Prolonged or severe hypoglycaemic episodes may be life-threatening.

In many patients, the signs and symptoms of neuroglycopenia are preceded by signs of adrenergic counter-regulation. Generally, the greater and more rapid the decline in blood glucose, the more marked is the phenomenon of counter-regulation and its symptoms.

Hypoglycaemia may be difficult to recognise in the elderly.
Close glucose monitoring is recommended and the insulin dose should be adjusted on an individual basis (see sections 4.4 and 4.8).
The prolonged effect of subcutaneous TOUJEO may delay recovery from hypoglycaemia.

If normal or decreased values for glycated haemoglobin are noted, the possibility of recurrent, unrecognised (especially nocturnal) episodes of hypoglycaemia must be considered.

Compliance of the patient with the dosage and dietary regimen, correct insulin administration and awareness of hypoglycaemia symptoms are essential to reduce the risk of hypoglycaemia.

Presence of factors which increase the susceptibility to hypoglycaemia requires particularly close monitoring and may necessitate dose adjustment. These factors include:

- change in the injection area
- increased insulin sensitivity (e.g. by removal of stress factors)
- unaccustomed, increased or prolonged physical exercise
- intercurrent illness (e.g. vomiting, diarrhoea)
- inadequate food intake
- alcohol consumption
- certain uncompensated endocrine disorders
- concomitant treatment with certain medicines (see section 4.5).

Renal impairment:

In patients with renal impairment, insulin requirements may be diminished due to reduced insulin metabolism.

In the elderly, progressive deterioration of renal function may lead to a steady decrease in insulin requirements.

Hepatic impairment:

In patients with severe hepatic impairment, insulin requirements may be diminished due to reduced capacity for gluconeogenesis and reduced insulin metabolism.

Anti-insulin antibodies:

In clinical studies comparing TOUJEO and LANTUS, anti-insulin antibodies were observed with similar frequencies in both treatment groups.

In rare cases, the presence of such anti-insulin antibodies may necessitate adjustment of the insulin dose in order to correct a tendency to hyperglycaemia or hypoglycaemia.

Diabetic retinopathy:

Long-term improved glycaemic control decreases the risk of progression of diabetic retinopathy. However, intensification of insulin therapy with abrupt improvement in glycaemic control may be associated with temporary worsening of diabetic retinopathy.

Lipodystrophy, lipohypertrophy and localized cutaneous amyloidosis:
Lipodystrophy and localized cutaneous amyloidosis may occur at the injection site.

In clinical studies with regimens which included insulin glargine, lipohypertrophy was observed in 1 to 2 % of patients, whereas lipodystrophy was uncommon.

Patients must be instructed to perform continuous rotation of the injection site within a given area 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.

Injection site reactions:
In TOUJEO clinical studies in adult patients, the incidence of overall injection site reactions was similar in TOUJEO-treated patients (2,5 %) and LANTUS-treated patients (2,8 %).
Most minor reactions to insulins usually resolve in a few days to a few weeks.

Sodium retention and oedema:
Insulin may cause, in rare cases, sodium retention and oedema, particularly if previously poor metabolic control is improved by intensified insulin therapy.

Intercurrent illness:

Intercurrent illness requires intensified metabolic monitoring. In many cases urine tests for ketones are indicated, and often it is necessary to adjust the insulin dose.

In patients with type 1 diabetes, carbohydrate supplies must be maintained even if patients are able to eat only little or no food, or are vomiting. In patients with type 1 diabetes, insulin must never be omitted entirely.

Combination of TOUJEO with pioglitazone:

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. This should be kept in mind if treatment with the combination of pioglitazone and {PRODUCT NAME] is considered. 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.

Medication errors:

The insulin label must always be checked before each injection to avoid medication errors between TOUJEO and other insulins.

To avoid dosing errors and potential overdose, the patients must also be instructed to never use a syringe to remove TOUJEO from the SoloStar pre-filled pen into a syringe.

Patients must also be instructed to not re-use needles. A new sterile needle must be attached before each injection. Re-use of needles increases the risk of blocked needles which may cause underdosing or overdosing. In the event of blocked needles, the patients

must follow the instructions described in Step 3 of the TOUJEO SoloStar Instructions for Use.

Patients must visually verify the number of selected units on the dose counter of the pen. Patients who are blind or have poor vision must be instructed to get help/assistance from another person who has good vision and is trained in using the insulin device.

4.5 Interaction with other medicines and other forms of interaction:

A number of substances affect glucose metabolism and may require insulin dose adjustment and particularly close monitoring.

The following substances may increase the blood glucose-lowering effect and susceptibility to hypoglycaemia: anti-hyperglycaemic medicines, ACE inhibitors, salicylates, disopyramide, fibrates, fluoxetine, MAO inhibitors including linezolid, pentoxifylline and sulfonamide antibiotics.

The following substances may reduce the blood glucose-lowering effect: corticosteroids, danazol, diazoxide, diuretics, sympathomimetic medicines (such as epinephrine, salbutamol, terbutaline), glucagon, isoniazid, phenothiazine derivatives, somatropin, thyroid hormones, oestrogens, progestogens (e.g. in oral contraceptives), protease inhibitors and atypical antipsychotic medicines (e.g. olanzapine and clozapine).

Beta-blockers, clonidine, lithium salts and alcohol may either potentiate or weaken the blood glucose-lowering effect of insulin.

Pentamidine may cause hypoglycaemia, which may sometimes be followed by hyperglycaemia.

In addition, under the influence of sympatholytic medicines such as beta-blockers, clonidine and reserpine, the signs of adrenergic counter-regulation may be reduced or absent.

4.6 Fertility, pregnancy and lactation:

Pregnancy:

Safety and efficacy in pregnancy have not been demonstrated.

Insulin requirements may decrease during the first trimester and generally increase during the second and third trimesters.

Immediately after delivery, insulin requirements decline rapidly.

Careful monitoring of glucose control is essential in such patients.

Patients with diabetes must inform their doctor if they are pregnant or are contemplating pregnancy.

Breastfeeding:

Lactating women may require adjustments in insulin dose and diet.

4.7 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.

This may constitute a risk in situations where these abilities are of special importance (e.g. driving a car or operating machinery).

Patients should be advised to take precautions to avoid hypoglycaemia whilst driving.

This is particularly important in those who have reduced or absent awareness of the warning symptoms of hypoglycaemia or have frequent episodes of hypoglycaemia. The advisability of driving should be considered in these circumstances.

4.8 Undesirable effects:

The following side effects were observed during clinical studies conducted with TOUJEO and during clinical experience with insulin glargine 100 U/mL.

The following CIOMS frequency rating is used, when applicable: very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1 000 to <1/100), rare (≥ 1/10 000 to < 1/1 000), very rare (< 1/10 000) and not known (cannot be estimated from available data).

Endocrine disorders:

Very common: hypoglycaemia

Hypoglycaemia, in general the most frequent adverse reaction of insulin therapy, may occur if the insulin dose is too high in relation to the insulin requirement

Frequency unknown: Insulin administration may cause anti-insulin antibodies

Metabolism and nutrition disorders:

Rare: sodium retention and oedema

Eye disorders:

Frequency unknown: A marked change in glycaemic control may cause temporary visual impairment, due to temporary alteration in the turgidity and refractive index of the lens

Skin and subcutaneous tissue disorders:

Common: lipohypertrophy

Uncommon: lipodystrophy

General disorders and administration site conditions:

Common: injection site reactions and local hypersensitivity reactions

Such reactions include redness, pain, itching, hives, swelling and inflammation

Rare: systemic allergic reactions

Immediate-type allergic reactions are rare

Such reactions to insulin (including insulin glargine) or the excipients may, for example, be associated with generalised skin reactions, angioedema, bronchospasm, and hypotension and anaphylactic shock, and may be life-threatening.

Post-marketing side effects:

Skin and subcutaneous tissue disorders:

Localized cutaneous amyloidosis at the injection site has occurred with insulins such as TOUJEO and delay insulin absorption. Hyperglycemia has been reported with repeated insulin injections into areas of cutaneous amyloidosis; hypoglycemia has been reported with a sudden change to an unaffected injection site. Continuous rotation of the injection site within a given area may help to reduce or prevent these reaction(see sections 4.2 and 4.4).

Paediatric population:

Safety and efficacy of TOUJEO have been demonstrated in a study in children aged 6 to less than 18 years. The frequency, type and severity of adverse reactions in the paediatric population do not indicate differences to the experience in the general diabetes population (see section 5.1). Clinical study safety data are not available for children under 6 years.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to:

- The Pharmacovigilance Unit at Sanofi: za.drugsafety@sanofi.com (email) or 011 256-3700 (tel), or
- SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**" found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose:

Signs and symptoms:

An excess of TOUJEO, relative to food intake, energy expenditure or both, may lead to severe and sometimes prolonged and life-threatening hypoglycaemia.

Management:

Mild episodes of hypoglycaemia can usually be treated with oral carbohydrates, e.g. glucose. Adjustments in medicine dosage, meal patterns or physical activity may be needed.
More severe episodes with coma, seizure or neurologic impairment may be treated with intramuscular/subcutaneous glucagon or concentrated intravenous glucose.
Sustained carbohydrate intake and observation may be necessary because hypoglycaemia may recur after apparent clinical recovery.

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic properties:

Category and class: A 21.1 Insulin preparations.
Pharmacotherapeutic group: Medicines used in diabetes, insulins and analogues for injection, long-acting.
ATC code: A10A E04.

The primary activity of insulin, including insulin glargine, is regulation of glucose metabolism.

The effect of insulin glargine U300 was observed beyond 24 hours (up to 36 hours) at clinically relevant doses.

In a clinical pharmacology study, intravenous use of insulin glargine and human insulin have been shown to be equipotent when given at the same doses.

Insulin glargine is metabolised into two active metabolites M1 (21A-Gly-insulin) and M2 (21A-Gly-des-30B-Thr-insulin).

The affinity of insulin glargine and its metabolites M1 and M2 for the human insulin receptor is similar to the one of human insulin.

Paediatric population:

The efficacy and safety of TOUJEO have been studied in a 1:1 randomised controlled clinical trial in children and adolescents with type 1 diabetes mellitus for a period of 26 weeks (n = 463). Patients in the TOUJEO arm included 73 children aged < 12 years and 160 children aged ≥ 12 years.

TOUJEO dosed once daily showed similar reduction in HbA1c and FPG from baseline to week 26 compared to insulin glargine 100 units/mL.

Overall the incidence of hypoglycaemia in patients in any category was similar in both treatment groups, with 97,9 % of patients in the TOUJEO group and 98,2 % in the insulin glargine 100 units/mL group reporting at least one event. Similarly, nocturnal hypoglycaemia was comparable in the TOUJEO and insulin glargine 100 units/mL treatment groups. The percentage of patients reporting severe hypoglycaemia was lower in patients in the TOUJEO group as compared to patients in the insulin glargine 100 units/mL group, 6 % and 8,8 % respectively.

The percentage of patients with hyperglycaemic episodes with ketosis was lower for TOUJEO versus insulin glargine 100 units/mL, 6,4 % and 11,8 %, respectively. No safety

issues were identified with TOUJEO with respect to adverse events and standard safety parameters.

Antibody development was sparse and had no clinical impact.

Efficacy and safety data for paediatric patients with type 2 diabetes mellitus have been extrapolated from data for adolescent and adult patients with type 1 diabetes mellitus and adult patients with type 2 diabetes mellitus. Results support the use of TOUJEO in paediatric patients with type 2 diabetes mellitus.

5.2 Pharmacokinetic properties:

Insulin glargine is a human insulin analogue that has been designed to have low aqueous solubility at neutral pH. At pH 4, insulin glargine is completely soluble. After injection into the subcutaneous tissue, the acidic solution is neutralised, leading to formation of a precipitate from which small amounts of insulin glargine are continuously released.

Absorption and distribution:

After subcutaneous injection of insulin glargine U300 in healthy subjects and diabetic patients, the insulin serum concentrations indicated slower and prolonged absorption for up to 36 hours. Concentrations were consistent with the time profile of the pharmacodynamic activity of insulin glargine U300.

Steady state level within the therapeutic range is reached after 3 – 4 days of daily insulin glargine U300 administration. After subcutaneous injection of insulin glargine U300, the intra-subject variability, defined as the coefficient of variation for the insulin exposure during 24 hours, was 17,4 % at steady state.

Metabolism:

After subcutaneous injection of insulin glargine U300 in healthy subjects and diabetic patients, insulin glargine is rapidly metabolised at the carboxyl terminus of the ß-chain with formation of two active metabolites M1 (21A-Gly-insulin) and M2 (21A-Gly-des-30B-Thr-insulin). In plasma, the principal circulating compound is the metabolite M1. The exposure to M1 increases with the administered dose of insulin glargine U300.

The pharmacokinetic and pharmacodynamic findings indicate that the effect of the subcutaneous injection with insulin glargine U300 is principally based on exposure to M1. Insulin glargine and the metabolite M2 were not detectable in the vast majority of subjects and, when they were detectable, their concentration was independent of the administered dose and formulation of insulin glargine.

Elimination:

The half-life of M1, the predominant metabolite of insulin glargine U300 after subcutaneous injection, is 18 – 19 hours independent of dose.

Special patient populations:

Elderly patients: The effect of age on the pharmacokinetics of insulin glargine U300 has not been studied.

Paediatric patients:

Population pharmacokinetic analysis was conducted for TOUJEO based on concentration data of its main metabolite M1 using data from 75 paediatric subjects (6 to < 18 years of age) with type 1 diabetes. Body mass was a significant covariate affecting the clearance of TOUJEO. After adjusting for body mass, the total exposure (AUC) to TOUJEO at steady state was independent of age.

Renal impairment: The effect of renal impairment on the pharmacokinetics of insulin glargine U300 has not been studied. In patients with renal impairment, insulin requirements may be diminished due to reduced insulin metabolism.

Hepatic impairment: The effect of hepatic impairment on the pharmacokinetics of insulin glargine U300 has not been studied. However, some studies with human insulin have shown increased circulating levels of insulin in patients with liver failure.

5.3 Preclinical safety data

No further information of relevance available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Zinc chloride

Metacresol 0,27 % *m/v* (as preservative)

Glycerol

Hydrochloride acid (for pH adjustment)

Sodium hydroxide (for pH adjustment)

Water for injection.

6.2 Incompatibilities

TOUJEO must not be mixed with any other insulin products. Mixing changes the time/action profile TOUJEO and causes precipitation.

TOUJEO must not be diluted.

Diluting changes the time/action profile of TOUJEO.

6.3 Shelf life

30 months.

6.4 Special precautions for storage

KEEP OUT OF REACH OF CHILDREN.

Unopened/not in-use pre-filled pen:

TOUJEO must be stored between 2 °C and 8 °C (in a refrigerator) and protected from light.

Do not allow the insulin to freeze, discard if frozen.

Do not put TOUJEO next to the freezer compartment or a freezer pack.

Opened/in-use pre-filled pen:

Opened pre-filled pen must be discarded after 42 days (6 weeks) from the first use.

The open pre-filled pen of TOUJEO should be kept away from direct heat and light, at room temperature (at or below 30 °C).

6.5 Nature and contents of container

Each TOUJEO SoloStar pre-filled disposable pen contains 1,5 mL (450 units) of solution for injection in a multidose colourless glass cartridge. The cartridge is closed on one end with a rubber plunger stopper and on the opposite end with a silver aluminium flanged cap with a punched laminated sealing disk. The outer cardboard box containing 3 or 5 disposable pens with a leaflet.

6.6 Special precautions for disposal:

Any unused medicine should be disposed of in accordance with local requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION:

sanofi-aventis south africa (pty) ltd

Hertford Office Park

90 Bekker Road

Midrand 2196

South Africa

Manufacturer:

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