TOUJEO is indicated to improve glycemic control in adults with diabetes mellitus.

Limitations of Use:

- Hypersensitivity to TOUJEO or one of its excipients (4)
- During episodes of hypoglycemia (4)
- Hypokalemia: Activity can occur. Discontinue TOUJEO, monitor and treat if indicated. (5.5, 6.1)
- Medication errors: Accidental mix-ups between insulin products can occur. Instruct patients to check insulin labels before injection. (5.4)
- Hypersensitivity reactions: Severe, life-threatening, generalized allergy, including anaphylaxis, can occur. Discontinue TOUJEO, monitor and treat if indicated. (5.5, 6.1)
- Fluid retention and heart failure with concomitant use of Thiazolidinediones (TZDs): Observe for signs and symptoms of heart failure; consider dosage reduction or discontinuation if heart failure occurs. (5.7)

Dosage and Administration:

- Individualize dose based on type of diabetes, metabolic needs, blood glucose monitoring results and glycemic control goal. (2.1, 2.2, 2.3)
- Administer subcutaneously once daily at any time during the day, at the same time every day. (2.1)
- Rotate injection sites to reduce the risk of lipodystrophy. (2.1)
- Do not dilute or mix with any other insulin or solution. (2.1)
- Closely monitor glucose when changing to TOUJEO and during initial weeks thereafter. (2.3)

Dosage Forms and Strengths:

- Injection: 300 units/mL insulin glargine in:
  - 1.5 mL TOUJEO SoloStar disposable prefilled pen (3)
  - 3 mL TOUJEO Max SoloStar disposable prefilled pen (3)

Contraindications:

- During episodes of hypoglycemia (4)
- Hypersensitivity to TOUJEO or one of its excipients (4)

Warnings and Precautions:

- Never share a TOUJEO SoloStar or TOUJEO Max SoloStar disposable prefilled pen between patients, even if the needle is changed. (5.1)
- Hyperglycemia or hypoglycemia with changes in insulin regimen: Carry out under close medical supervision. (5.2)
- Hypoglycemia: May be life-threatening. Increase frequency of glucose monitoring with changes to: insulin dosage, coadministered glucose-lowering medications, meal pattern, physical activity, and in patients with renal impairment or hepatic impairment or hypoglycemia unawareness. (5.3, 6.1)
- Medication errors: Accidental mix-ups between insulin products can occur. Instruct patients to check insulin labels before injection. (5.4)
- Hypersensitivity reactions: Severe, life-threatening, generalized allergy, including anaphylaxis, can occur. Discontinue TOUJEO, monitor and treat if indicated. (5.5, 6.1)
- Fluid retention and heart failure with concomitant use of Thiazolidinediones (TZDs): Observe for signs and symptoms of heart failure; consider dosage reduction or discontinuation if heart failure occurs. (5.7)

Adverse Reactions:

- Hydroxyurea, allergic reactions, injection site reaction, lipodystrophy, pruritus, rash, edema, and weight gain. (6.1, 6.2)

To report SUSPECTED ADVERSE REACTIONS, contact sanofi-aventis at 1-800-633-1610 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Drug Interactions:

- Drugs that affect glucose metabolism: Adjustment of insulin dosage may be needed; closely monitor blood glucose. (7)
- Antiadrenergic drugs (e.g., beta-blockers, clonidine, guanethidine, and reserpine): Signs and symptoms of hypoglycemia may be reduced or absent. (7)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 10/2018
Pharmacology (12.2)

Symptomatic awareness of hypoglycemia may be less pronounced in patients with type 1 diabetes. Severe hypoglycemia can cause seizures, may be life-threatening, or cause death. Hypoglycemia can happen suddenly and symptoms may differ in each individual and change over time in the same individual. Symptomatic awareness of hypoglycemia may be less pronounced in patients with longstanding diabetes, in patients with diabetic nerve disease, in patients using medications that block the sympathetic nervous system (e.g., beta-blockers) [see Drug Interactions (7)] or in patients who experience recurrent hypoglycemia.

Risk Factors for Hypoglycemia

The timing or frequency of hypoglycemia usually reflects the time-action profile of the administered insulin formulation. As with all insulin preparations, the glucose lowering effect time course of TOUJEO may vary in different individuals or at different times in the same individual and depends on many conditions, including the area of injection as well as the injection site blood supply and temperature [see Clinical Pharmacology (12.2)]. Other factors which may increase the risk of hypoglycemia include changes in meal pattern (e.g., macronutrient content or timing of meals), changes in level of physical activity, or changes to coadministered medication [see Drug Interactions (7)]. Patients with renal or hepatic impairment may be at higher risk of hypoglycemia [see Use in Specific Populations (8.6, 8.7)].

Risk Mitigation Strategies for Hypoglycemia

Patients and caregivers must be educated to recognize and manage hypoglycemia. Self-monitoring of blood glucose plays an essential role in the prevention and management of hypoglycemia. In patients at higher risk for hypoglycemia and patients who have reduced symptomatic awareness of hypoglycemia, increased frequency of blood glucose monitoring is recommended. To minimize the risk of hypoglycemia do not administer TOUJEO intravenously, intramuscularly, or in an insulin pump, or dilute or mix TOUJEO with any other insulin products or solutions.

5.4 Medication Errors

Accidental mix-ups between basal insulin products and other insulin, particularly rapid-acting insulins, have been reported. To avoid medication errors between TOUJEO and other insulins, instruct patients to always check the insulin label before each injection.

To avoid dosing errors and potential overdose, never use a syringe to remove TOUJEO from the TOUJEO SoloStar or TOUJEO Max SoloStar prefilled pen into a syringe for administration [see Doseage and Administration (2.4) and Warnings and Precautions (5.3)].

5.5 Hypersensitivity and Allergic Reactions

Severe, life-threatening, generalized allergy, including anaphylaxis, can occur with insulin products, including TOUJEO. If hypersensitivity occurs, discontinue TOUJEO; treat per standard of care and monitor until symptoms and signs resolve [see Adverse Reactions (6)]. TOUJEO is contraindicated in patients who have had hypersensitivity reactions to insulin glargin or other of the excipients [see Warnings and Precautions (5.2)].

5.6 Hypokalemia

All insulin products, including TOUJEO, cause a shift in potassium from the extracellular to the intracellular compartment, leading to hypokalemia. Untreated hypokalemia may cause respiratory paralysis, ventricular arrhythmia, and death. Monitor potassium levels in patients at risk for hypokalemia, if indicated (e.g., patients using potassium-sparing medications, patients taking medications sensitive to changes in serum potassium concentration).

Fluid Retention and Heart Failure with Concomitant Use of PPAR-gamma Agonists

Thiazolidinediones (TZDs), which are peroxisome proliferator-activated receptor (PPAR)-gamma agonists, can cause dose-related fluid retention, particularly when used in combination with insulin. Fluid retention may limit the ability to control or extend heart failure. Patients treated with insulin, including TOUJEO, and a PPAR-gamma agonist should be observed for signs and symptoms of heart failure. If heart failure develops, it should be managed according to current standards of care, and discontinuation or dose reduction of the PPAR-gamma agonist must be considered.

6 ADVERSE REACTIONS

The following adverse reactions are discussed elsewhere: Hypoglycemia [see Warnings and Precautions (5.3)] Medication errors [see Warnings and Precautions (5.4)] Hypersensitivity and allergic reactions [see Warnings and Precautions (5.5)] Hypokalemia [see Warnings and Precautions (5.6)]

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug, and may not reflect the rates actually observed in clinical practice.

The data in Table 1 reflect the exposure of 304 patients with type 1 diabetes to TOUJEO with mean exposure duration of 23 weeks. The type 1 diabetes population had the following characteristics: Mean age was 46 years and mean duration of diabetes was 21 years. Fifty-five percent were male, 60% were Caucasian, 10% were Black or African American, and 8% were Hispanic. At baseline, the mean eGFR was 82 mL/min/1.73 m² and 3% of patients had eGFR ≤ 60 mL/min/1.73 m². The mean BMI was 28 kg/m². HbA1c at baseline was greater or equal to 8% in 66% of patients.

The data in Table 2 reflect the exposure of 1242 patients with type 2 diabetes to TOUJEO with mean exposure duration of 25 weeks. The type 2 diabetes population had the following characteristics: Mean age was 54 years and mean duration of diabetes was 12 years. Fifty-five percent were male, 78% were Caucasian, 7% were Black or African American, and 17% were Hispanic. At baseline, the mean eGFR was 79 mL/min/1.73 m² and 21% of patients had an eGFR ≤ 60 mL/min/1.73 m². The mean BMI was 35 kg/m². HbA1c at baseline was greater or equal to 8% in 66% of patients.

Common adverse reactions were defined as reactions occurring in ≥5% of the population studied. Common adverse reactions occurring for TOUJEO-treated subjects during clinical trials in patients with type 1 diabetes mellitus and type 2 diabetes mellitus are listed in Table 1 and Table 2, respectively. Hypoglycemia is discussed in a dedicated subsection below.

Table 1: Adverse Reactions in Two Pooled Clinical Trials of 26 Weeks and 16 Weeks Duration in Adults with Type 1 Diabetes (with incidence ≥5%)

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;meatlike insulin&quot; refers to insulin glulisine, insulin isoph., or insulin aspart.</td>
<td></td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>9.5</td>
</tr>
</tbody>
</table>

Table 2: Adverse Reactions in Three Pooled Clinical Trials of 26 Weeks Duration in Adults with Type 2 Diabetes (with incidence ≥5%)

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nasopharyngitis</td>
<td>12.8</td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>5.7</td>
</tr>
</tbody>
</table>

TOUJEO % (n=1242)
Table 3: Clinically Significant Drug Interactions with TOUJEO (continued)

<table>
<thead>
<tr>
<th>Drugs That May Increase or Decrease the Blood Glucose Lowering Effect of TOUJEO</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Drugs</strong>:</td>
</tr>
<tr>
<td><strong>Drugs That May Blunt Signs and Symptoms of Hypoglycemia</strong>:</td>
</tr>
<tr>
<td><strong>Intervention</strong>:</td>
</tr>
</tbody>
</table>

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Published studies with use of insulin glargine during pregnancy have not reported a clear association with insulin glargine and adverse developmental outcomes [see Data]. There are risks to the mother and fetus associated with poorly controlled diabetes in pregnancy [see Clinical Considerations].

Rats and rabbits were exposed to insulin glargine in animal reproduction studies during organogenesis, respectively 50 times and 10 times the human subcutaneous dose of 0.2 Unit/kg/day. Overall, the effects of insulin glargine did not generally differ from those observed with regular human insulin [see Data]. The estimated background risk of major birth defects is 6% to 10% in women with pregestational diabetes among type 1 diabetes mellitus, and has been reported to be as high as 20% to 25% in women with a HbA1c >10. The estimated background risk of miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Clinical Considerations

Disease-associated maternal and/or embryo/fetal risk

Poorly controlled diabetes in pregnancy increases the maternal risk for diabetic ketoacidosis, preeclampsia, spontaneous abortions, preterm delivery, stillbirth, and delivery complications. Poorly controlled diabetes increases the fetal risk for major birth defects, stillbirth, and macrosomia-related morbidity.

Data

Human data

Published data do not report a clear association with insulin glargine and major birth defects, miscarriage, or adverse maternal or fetal outcomes when insulin glargine is used during pregnancy. However, these studies cannot definitively establish the absence of any risk because of methodological limitations including small sample size and some lacking comparator groups.

Animal data

Subcutaneous reproduction and teratology studies have been performed with insulin glargine and regular human insulin in rats and Himalayan rabbits. Insulin glargine was given to female rats before mating, during mating, and throughout pregnancy at doses up to 0.36 mg/kg/day, which is approximately 50 times the recommended human subcutaneous starting dose of 0.2 Units/kg/day (0.007 mg/kg/day). In rabbits, doses of 0.072 mg/kg/day, which is approximately 10 times the recommended human subcutaneous starting dose of 0.2 Units/kg/day (0.007 mg/kg/day), were administered during organogenesis. The effects of insulin glargine did not generally differ from those observed with regular human insulin in rats or rabbits. However, in rabbits, five fetuses from two litters of the high-dose group exhibited dilation of the cerebral ventricles. Fertility and early embryonic development appeared normal.

8.2 Lactation

Risk Summary

There are either no or only limited data on the presence of insulin glargine in human milk, the effects on breastfed infant, or the effects on milk production. Endogenous insulin is present in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for TOUJEO, and any potential adverse effects on the breastfed child from TOUJEO or from the underlying maternal condition.

8.4 Pediatric Use

No overall differences in effectiveness and safety were observed in subgroup analyses based on BMI across the treatment groups.

No overall differences in effectiveness and safety were observed in the subgroup analyses across the age groups.

Nevertheless, caution should be exercised when TOUJEO is administered to geriatric patients. In elderly patients with diabetes, the initial dosing, dose increments, and maintenance dosage should be conservative to avoid hypoglycemia [see Warnings and Precautions (5.3), Adverse Reactions (6), and Clinical Studies (14)].

8.6 Hepatic Impairment

The effect of hepatic impairment on the pharmacokinetics of TOUJEO has not been studied. Frequent glucose monitoring and dose adjustment may be necessary for TOUJEO in patients with hepatic impairment [see Warnings and Precautions (5.3)].

8.7 Renal Impairment

The effect of renal impairment on the pharmacokinetics of TOUJEO has not been studied. Some studies with human insulin have shown increased circulating levels of insulin in patients with renal failure. Frequent glucose monitoring and dose adjustment may be necessary for TOUJEO in patients with renal impairment [see Warnings and Precautions (5.3)].

8.8 Obesity

No overall differences in effectiveness and safety were observed in subgroup analyses based on BMI.

10 GENETIC USE

Excess insulin administration may cause hypoglycemia and hypokalemia [see Warnings and Precautions (5.3, 5.6)]. Mild episodes of hypoglycemia can be treated with oral glucose. Adjustments in drug dosage, meal patterns, or physical activity level may be needed. More severe episodes of hypoglycemia with coma, seizure, or neurologic impairment may be treated with intramuscular/subcutaneous...
TOUJEO (insulin glargine injection) is a long-acting insulin supplied as a sterile solution for subcutaneous injection containing 300 units/mL of insulin glargine.

Insulin glargine is a human insulin analog produced by recombinant DNA technology utilizing a nonpathogenic laboratory strain of Escherichia coli (K12) as the production organism. Insulin glargine differs from human insulin in that the amino acid asparagine at position A21 is replaced by glycine and two arginines in the C terminus of the B-chain. Chemically, insulin glargine is 21A-Gly-31-A21-Di-Arg-human insulin and has the empirical formula C_{244}H_{287}N_{132}O_{104}S_{6} and a molecular weight of 6063. Insulin glargine has the following structural formula:

\[
\text{C}_{244}\text{H}_{287}\text{N}_{132}\text{O}_{104}\text{S}_{6}
\]

Each milliliter of TOUJEO contains 300 units (10.81 mg) insulin glargine dissolved in a clear aqueous fluid.

The 3 mL TOUJEO SoloStar disposable prefilled pen presentation contains the following inactive ingredients per mL: 90 mcg zinc, 2.7 mg m-cresol, 20 mg glycerol 85%, and water for injection.

The 1.5 mL TOUJEO SoloStar disposable prefilled pen presentation contains the following inactive ingredients per mL: 90 mcg zinc, 2.7 mg m-cresol, 20 mg glycerol 85%, and water for injection.

Insulin glargine was not mutagenic in tests for detection of gene mutations in bacteria and mammalian cells (Ames and HGPRT test) and in tests for detection of chromosomal aberrations (cytogenetics in vitro in V79 cells and in vivo in Chinese hamsters). In a combined fertility and prenatal and postnatal study in male and female rats at subcutaneous doses up to 0.36 mg/kg/day, which was approximately 50 times the recommended human subcutaneous starting dose of 0.2 Units/kg/day (0.007 mg/kg/day), the findings in female mice were not conclusive due to excessive mortality in all dose groups during the study. Histocytomas were found at injection sites in male rats (statistically significant) and male mice (not statistically significant) in acid vehicle containing groups. These tumors were not found in female animals, in saline control, or insulin comparator groups using a different vehicle. The relevance of these findings to humans is unknown.

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compared to LANTUS (Table 5). Patients treated with TOUJEO used 11% more basal insulin than patients treated with LANTUS. There were no clinically important differences in body weight between treatment groups.

In two open-label, controlled studies (n=1670), adults with type 2 diabetes mellitus were randomized to either TOUJEO or LANTUS once daily for 26 weeks as part of a regimen of combination therapy with noninsulin antidiabetic drugs. At the time of randomization, 808 patients were treated with basal insulin for more than 6 months (study C) and 862 patients were insulin-naïve (study D).

In Study C, the average age was 58.2 years. The majority of patients were White (93.6%) and 45.9% were male; 32.8% of patients had GFR >90 mL/min/1.73 m². The mean BMI was approximately 34.8 kg/m². At week 26, treatment with TOUJEO provided a mean reduction in HbA1c that met the prespecified noninferiority margin compared to LANTUS (Table 5). Patients treated with TOUJEO used 15% more basal insulin than patients treated with LANTUS. There were no clinically important differences in body weight between treatment groups.

In Study D, the average age was 57.7 years. The majority of patients were White (78%) and 57.7% were male; 29% of patients had GFR >90 mL/min/1.73 m². The mean BMI was approximately 33 kg/m². At week 26, treatment with TOUJEO provided a mean reduction in HbA1c that met the prespecified noninferiority margin compared to LANTUS (Table 5). Patients treated with TOUJEO used 15% more basal insulin than patients treated with LANTUS. There were no clinically important differences in body weight between treatment groups.

### Table 5: Type 2 Diabetes Mellitus – Adult

<table>
<thead>
<tr>
<th>Treatment duration</th>
<th>Study B</th>
<th>Study C</th>
<th>Study D</th>
</tr>
</thead>
<tbody>
<tr>
<td>26 weeks</td>
<td>26 weeks</td>
<td>26 weeks</td>
<td>26 weeks</td>
</tr>
</tbody>
</table>

**Treatment in combination with**

<table>
<thead>
<tr>
<th>Mealt ime insulin analog = metformin</th>
<th>Noninsulin antidiabetic drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>TOUJEO</td>
<td>LANTUS</td>
</tr>
<tr>
<td>Number of patients treated</td>
<td>404</td>
</tr>
<tr>
<td>HbA1c</td>
<td>8.13</td>
</tr>
<tr>
<td>Baseline mean</td>
<td>8.14</td>
</tr>
<tr>
<td>Adjusted mean change from baseline</td>
<td>-0.90</td>
</tr>
<tr>
<td>Adjusted mean difference</td>
<td>-0.03</td>
</tr>
<tr>
<td>[95% Confidence interval]</td>
<td>[-0.14 to 0.08]</td>
</tr>
<tr>
<td>Fasting Plasma Glucose (mg/dL)</td>
<td>157</td>
</tr>
<tr>
<td>Baseline mean</td>
<td>160</td>
</tr>
<tr>
<td>Adjusted mean change from baseline</td>
<td>-29</td>
</tr>
<tr>
<td>Adjusted mean difference</td>
<td>0.8</td>
</tr>
<tr>
<td>[95% Confidence interval]</td>
<td>[-5 to 7]</td>
</tr>
</tbody>
</table>

TOUJEO: Total volume: Concentration, Total units available in presentation, Max dose per injection, Dose increment, NDC number, Package size.

TOUJEO Total volume: Concentration, Total units available in presentation, Max dose per injection, Dose increment, NDC number, Package size.

Max SoloStar disposable prefilled pen: 3 mL 300 units/mL 900 units 160 units 2 units 0024-5896-03 3 pens/pack

TOUJEO Total volume: Concentration, Total units available in presentation, Max dose per injection, Dose increment, NDC number, Package size.

Max SoloStar disposable prefilled pen: 3 mL 300 units/mL 900 units 160 units 2 units 0024-5871-02 2 pens/pack

### Note

- TOUJEO SoloStar disposable prefilled pen should not be stored in the freezer and should not be allowed to freeze. Discard TOUJEO disposable prefilled pen if it has been frozen. Protect TOUJEO SoloStar/TOUJEO Max SoloStar from direct heat and light.
- Storage conditions are summarized in the following table:

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Condition</th>
<th>Units</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>In-use (unopened)</td>
<td>Refrigerated</td>
<td>36°F-46°F (2°C-8°C)</td>
<td>1.5 mL TOUJEO SoloStar disposable prefilled pen</td>
</tr>
<tr>
<td>In-use (opened)</td>
<td>Room temperature only</td>
<td>(Do not refrigerate) below 89°F (30°C)</td>
<td>3 mL TOUJEO Max SoloStar disposable prefilled pen</td>
</tr>
</tbody>
</table>

- To prevent degradation, always store the prefilled pens with the cap on during in-use period.

### 17 PATIENT COUNSELING INFORMATION

Advis e the patient to read the FDA-approved patient labeling (Patient Information and Instructions for Use).

Never Share a TOUJEO SoloStar or TOUJEO Max SoloStar Pen Between Patients

### Medication Errors

**See Warnings and Precautions (5.4).**

Inform patients that if they change to TOUJEO from other basal insulins they may experience higher average fasting plasma glucose levels in the first weeks of therapy. Advise patients to monitor glucose levels and report any symptoms of hypoglycemia.

**Warning:**

Inform patients that hypoglycemia is the most common adverse reaction with insulin. Inform patients of the symptoms of hypoglycemia. Inform patients that the ability to concentrate and react may be impaired as a result of hypoglycemia. This may present a risk in situations where these abilities are especially important, such as driving or operating other machinery. Advise patients who frequent hypoglycemia or reduced or absent warning signs of hypoglycemia to use caution when driving or operating machinery.

**Warning:**

Inform patients that hypoglycemia is the most common adverse reaction with insulin. Inform patients of the symptoms of hypoglycemia. Inform patients that the ability to concentrate and react may be impaired as a result of hypoglycemia. This may present a risk in situations where these abilities are especially important, such as driving or operating other machinery. Advise patients who frequent hypoglycemia or reduced or absent warning signs of hypoglycemia to use caution when driving or operating machinery.

### 18 HOW SUPPLIED/STORAGE AND HANDLING

**16.1 How Supplied**

TOUJEO is supplied as a clear and colorless solution containing 300 units per mL (U-300) of insulin glargine and is available in 2 disposable prefilled pen presentations:

<table>
<thead>
<tr>
<th>TOUJEO</th>
<th>Total volume</th>
<th>Concentration</th>
<th>Total units available in presentation</th>
<th>Max dose per injection</th>
<th>Dose increment</th>
<th>NDC number</th>
<th>Package size</th>
</tr>
</thead>
<tbody>
<tr>
<td>SoloStar disposable prefilled pen</td>
<td>1.5 mL</td>
<td>300 units/mL</td>
<td>450 units</td>
<td>80 units</td>
<td>1 unit</td>
<td>0024-5896-03</td>
<td>3 pens/pack</td>
</tr>
</tbody>
</table>

TOUJEO: 3 mL 300 units/mL 900 units 160 units 2 units 0024-5871-02 2 pens/pack

**Note:**

- TOUJEO SoloStar prefilled pen contains 450 units of TOUJEO. It delivers 1 to 80 units in a single injection. The dose can be adjusted by 1 unit at a time.

- TOUJEO Max SoloStar disposable prefilled pen contains 900 units of TOUJEO. It delivers 1 to 80 units in a single injection. The dose can be adjusted by 1 unit at a time.

- TOUJEO SoloStar disposable prefilled pen contains 450 units of TOUJEO. It delivers 1 to 80 units in a single injection. The dose can be adjusted by 1 unit at a time.
# TOUJEO Max SoloStar Prefilled Pen

TOUJEO Max SoloStar prefilled pen contains 900 units of TOUJEO. It delivers 2 to 160 units in a single injection. The dose can be adjusted by 2 units at a time. If safety tests are not performed before first use of a new pen, insulin underdose can occur. To reduce potential underdose, this pen is recommended for patients requiring at least 20 units per day.

Instruct patients to not re-use needles. A new 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 needle, the patients must follow the instructions described in Step 3 of the Instructions for Use.

## Administration

TOUJEO must only be used if the solution is clear and colorless with no particles visible. Patients must be advised that TOUJEO must NOT be diluted or mixed with any other insulin or solution.

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Bridgewater, NJ 08807

LANTUS, TOUJEO, SoloStar, and TOUJEO Max SoloStar are registered trademarks of sanofi-aventis U.S. LLC.

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### Patient Information

**TOUJEO® (Too-Jay-o)**

(Insulin glargine injection)

300 units/mL (U-300)

for subcutaneous use

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**Do not share your TOUJEO SoloStar® or TOUJEO Max SoloStar® pen with other people, even if the needle has been changed. You may give other people a serious infection, or get a serious infection from them.**

**What is TOUJEO?**

- TOUJEO is a long-acting man-made insulin used to control high blood sugar in adults with diabetes mellitus.
- TOUJEO is not for use to treat diabetic ketoacidosis.
- It is not known if TOUJEO is safe and effective in children.

**Who should not use TOUJEO?**

Do not use TOUJEO if you:

- are having an episode of low blood sugar (hypoglycemia)
- have an allergy to insulin glargine or any of the ingredients in TOUJEO. See the end of this Patient Information leaflet for a complete list of ingredients in TOUJEO.

**What should I tell my healthcare provider before using TOUJEO?**

Before using TOUJEO, tell your healthcare provider about all your medical conditions, including if you:

- have liver or kidney problems
- take other medicines, especially ones called TZDs (thiazolidinediones).
- have heart failure or other heart problems. If you have heart failure, it may get worse while you take TZDs with TOUJEO.
- are pregnant, planning to become pregnant, or are breastfeeding. It is not known if TOUJEO may harm your unborn or breastfeeding baby.
- tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

**Before you start using TOUJEO, talk to your healthcare provider about low blood sugar and how to manage it.**

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### How should I use TOUJEO?

- TOUJEO is available in two disposable prefilled pens: TOUJEO SoloStar and TOUJEO Max SoloStar. Your healthcare provider will tell you which TOUJEO Pen is right for you.
- Read the detailed Instructions for Use that come with your TOUJEO SoloStar or TOUJEO Max SoloStar disposable prefilled pen.
- Use TOUJEO exactly as your healthcare provider tells you to. Your healthcare provider should tell you how much TOUJEO to use and when to use it.
- Know the amount of TOUJEO you use. Do not change the amount of TOUJEO you use unless your healthcare provider tells you to.
- Check your insulin label each time you give your injection to make sure you are using the correct insulin.
- Do not use a syringe to remove TOUJEO from your TOUJEO SoloStar or TOUJEO Max SoloStar disposable prefilled pen. This can cause you to give yourself too much insulin. TOUJEO has 3 times as much insulin in 1 mL compared to other standard insulin pens.
- Do not re-use needles. Always use a new needle for each injection. Reusing needles increases your chance of having blocked needles, which can cause you to get the wrong dose of TOUJEO. Using a new needle for each injection also lowers your risk of getting an infection. If your needle is blocked, follow the instructions in Step 3 of the Instructions for Use.
- TOUJEO should be used 1 time each day and at the same time each day.
- TOUJEO is injected under your skin (subcutaneously). Do not use TOUJEO in an insulin pump or inject TOUJEO into your vein (intravenously).
- Change (rotate) your injection sites within the area you choose with each dose. Do not use the exact spot for each injection.
- Do not mix TOUJEO with any other type of insulin or liquid medicine.
- Check your blood sugar levels. Ask your healthcare provider what your blood sugar should be and when you should check your blood sugar levels.

**Keep TOUJEO and all medicines out of the reach of children.**

**Your dose of TOUJEO may need to change because of:**

- a change in level of physical activity or exercise, weight gain or loss, increased stress, illness, change in diet, or because of other medicines you take.

**What should I avoid while using TOUJEO?**

While using TOUJEO do not:

- drive or operate heavy machinery, until you know how TOUJEO affects you
- drink alcohol or use over-the-counter medicines that contain alcohol
What are the possible side effects of TOUJEO?
TOUJEO may cause serious side effects that can lead to death, including:

- low blood sugar (hypoglycemia). Signs and symptoms that may indicate low blood sugar include:
  - dizziness or light-headedness, sweating, confusion
  - headache, blurred vision, slurred speech, shakiness, fast heartbeat, anxiety, irritability or mood change, hunger
- severe allergic reaction (whole body reaction). Get medical help right away if you have any of these signs or symptoms of a severe allergic reaction:
  - a rash over your whole body, trouble breathing, a fast heartbeat, or swelling
- low potassium in your blood (hypokalemia).
- heart failure. Taking certain diabetes pills called TZDs (thiazolidinediones) with TOUJEO may cause heart failure in some people. This can happen even if you have never had heart failure or heart problems before. If you already have heart failure it may get worse while you take TZDs with TOUJEO. Your healthcare provider should monitor you closely while you are taking TZDs with TOUJEO. Tell your healthcare provider if you have any new or worse symptoms of heart failure including:
  - shortness of breath, swelling of your ankles or feet, sudden weight gain

Treatment with TZDs and TOUJEO may need to be changed or stopped by your healthcare provider if you have new or worse heart failure.

Get emergency medical help if you have:
- trouble breathing, shortness of breath, fast heartbeat, swelling of your face, tongue, or throat, sweating, extreme drowsiness, dizziness, confusion.

The most common side effects of TOUJEO include:
- low blood sugar (hypoglycemia), weight gain, itching, rash, swelling, allergic reactions, including reactions at your injection site, skin thickening or pits at the injection site (lipodystrophy).

These are not all the possible side effects of TOUJEO. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of TOUJEO.
Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use TOUJEO for a condition for which it was not prescribed. Do not give TOUJEO to other people, even if they have the same symptoms that you have. It may harm them.

This Patient Information leaflet summarizes the most important information about TOUJEO. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about TOUJEO that is written for health professionals.

What are the ingredients in TOUJEO?
- Active ingredient: insulin glargine
- Inactive ingredients: zinc, m-cresol, glycerol, and water for injection. Hydrochloric acid and sodium hydroxide may be added to adjust the pH.

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For more information, go to www.TOUJEO.com or call 1-800-633-1610.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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