



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

**Public Summary**

<b>Summary for ARTG Entry:</b>	223457	TOUJEO SOLOSTAR insulin glargine 300 units/mL solution for injection injector pen
<b>ARTG entry for</b>	Medicine Registered	
<b>Sponsor</b>	Sanofi-Aventis Australia Pty Ltd	
<b>Postal Address</b>	Locked Bag 2227, NORTH RYDE BC, NSW, 1670 Australia	
<b>ARTG Start Date</b>	30/06/2015	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	Drug Safety Evaluation Branch	

**Conditions**

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Conditions Applying to Therapeutic Goods Accepted for Registration or Listing as Goods Currently Supplied at the Commencement of the Therapeutic Goods Act 1989"

Except where the sponsor has been contracted by an overseas party to manufacturer the goods and that party will be responsible for placing the goods on the market in countries other than Australia, the sponsor must have and shall retain, while the goods remain listed, evidence necessary to substantiate and support the accuracy of the indications in relation to the listed goods, and upon the request of the Head, Office of Prescription Medicines Authorisation Branch, Therapeutic Goods Administration, shall produce such evidence to this officer.

The conditions applying to these goods when they are exported from Australia are given below:

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995, other than condition No. 8 and condition No. 9.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995, other than condition No.11

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

The therapeutic goods grouped in this registration/listing as export only goods under the following names are included in the Australian Register of Therapeutic Goods and may not be supplied in Australia. Export Name(s) to be added:

**Products**

**1 . TOUJEO SOLOSTAR insulin glargine 300 units/mL solution for injection injector pen**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	14/05/2021
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**Permitted Indications**

No Permitted Indications included on Record

**Indication Requirements**

No Indication Requirements included on Record

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

Treatment of diabetes mellitus in patients 6 years of age and older.

**Warnings**

See Product Information and Consumer Medicine Information for this product

**Additional Product information**

**Container information**

Type	Material	Life Time	Temperature	Closure	Conditions
Cartridge	Glass	36 Months	Store at 2 to 8 degrees Celsius	Not recorded	Do not Freeze Refrigerate

**Pack Size/Poison information**



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**Pack Size**

5 pen injector  
3 pen injector  
1 pen injector

**Poison Schedule**

(S4) Prescription Only Medicine  
(S4) Prescription Only Medicine  
(S4) Prescription Only Medicine

**Components**

1 . TOUJEO insulin glargine 300 units/mL solution for injection injector pen

<b>Dosage Form</b>	Injection, solution
<b>Route of Administration</b>	Subcutaneous
<b>Visual Identification</b>	Clear colourless solution, practically free from particles

**Active Ingredients**

<b>Insulin glargine</b>	<b>10.91 mg/mL</b>
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**Other Ingredients (Excipients)**

glycerol  
hydrochloric acid  
metacresol  
sodium hydroxide  
water for injections  
zinc chloride

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