



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 223457 TOUJEO insulin glargine 300 units/mL solution for injection injector pen

ARTG entry for Medicine Registered
Sponsor Sanofi-Aventis Australia Pty Ltd
Postal Address Locked Bag 2227, NORTH RYDE BC, NSW, 1670
 Australia
ARTG Start Date 30/06/2015
Product category Medicine
Status Active
Approval area Drug Safety Evaluation Branch

Conditions

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.

Products

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

Product Type	Single Medicine Product	Effective date	24/07/2018
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Permitted Indications

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

Treatment of diabetes mellitus in adults

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	Refrigerate Do not Freeze

Pack Size/Poison information

Pack Size	Poison Schedule
1 pen injector	(S4) Prescription Only Medicine
5 pen injector	(S4) Prescription Only Medicine
3 pen injector	(S4) Prescription Only Medicine

Components

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

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

Active Ingredients

Insulin glargine	10.91 mg/mL
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