




Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	379334	MOUNJARO tirzepatide 15 mg/0.5 mL solution for injection pre-filled pen
ARTG entry for	Medicine Registered	
Sponsor	Eli Lilly Australia Pty Ltd	
Postal Address	Level 9 60 Margaret Street, Sydney, NSW, 2000 Australia	
ARTG Start Date	23/12/2022	
Product Category	Medicine	
Status	Active	
Approval Area	Drug Safety Evaluation Branch	


**Medicine under
additional monitoring**

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"

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 February 1992, 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 February 1992, other than condition No. 11.

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 . MOUNJARO tirzepatide 15 mg/0.5 mL solution for injection pre-filled pen

Product Type	Single Medicine Product	Effective Date	5/01/2024
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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

Type 2 Diabetes Mellitus; MOUNJARO is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise, as monotherapy when metformin is not tolerated or contraindicated, in addition to other medicinal products for the treatment of type 2 diabetes.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

This product is included in the Black Triangle Scheme



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Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Syringe	Glass Type I Clear	2 Years	Store at 2 to 8 degrees Celsius	Neither child resistant closure nor restricted flow insert	Refrigerate Store in Original Container Do not Shake Do not Freeze Protect from Light

Pack Size/Poison information

Pack Size	Poison Schedule
2	(S4) Prescription Only Medicine
4	(S4) Prescription Only Medicine

Components

1 . MOUNJARO tirzepatide 15 mg/0.5 mL solution for injection pre-filled pen

Dosage Form	Injection, solution
Route of Administration	Subcutaneous
Visual Identification	clear, colourless to slightly yellow, sterile solution

Active Ingredients

tirzepatide	15 mg
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Other Ingredients (Excipients)

dibasic sodium phosphate heptahydrate
hydrochloric acid
sodium chloride
sodium hydroxide
water for injections

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