Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 407051 MOUNJARO tirzepatide 7.5 mg/0.5 mL solution for injection vial

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	10/07/2023
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 partry 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 7.5 mg/0.5 mL solution for injection vial

Product Type Single Medicine Product **Effective Date** 17/08/2023

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

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Vial	Glass Type I Clear	12 Months	Store at 2 to 8 degrees Celsius	Neither child resistant closure nor restricted flow insert	Do not Freeze Do not Shake Protect from Light Store in Original Container Refrigerate

Pack Size/Poison information

Pack Size	Poison Schedule
1	(S4) Prescription Only Medicine

Components

1 . MOUNJARO tirzepatide 7.5 mg/0.5 mL solution for injection vial

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

Active Ingredients

tirzepatide	**7.5 mg**

Other Ingredients (Excipients)

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

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