

Drugs@FDA: FDA-Approved Drugs

[Home \(index.cfm\)](#) | [Previous Page](#)

New Drug Application (NDA): 215866
Company: ELI LILLY AND CO

- ☒ EMAIL (MAILTO:7SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=215866)
- [Medication Guide \(https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/215866Orig1s002s006lbl.pdf#page=20\)](https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/215866Orig1s002s006lbl.pdf#page=20)

Products on NDA 215866

CSVExcelPrint

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
MOUNJARO	TIRZEPATIDE	2.5MG/0.5ML (2.5MG/0.5ML)	SOLUTION;SUBCUTANEOUS	Prescription	None	Yes	Yes
MOUNJARO	TIRZEPATIDE	5MG/0.5ML (5MG/0.5ML)	SOLUTION;SUBCUTANEOUS	Prescription	None	Yes	Yes
MOUNJARO	TIRZEPATIDE	7.5MG/0.5ML (7.5MG/0.5ML)	SOLUTION;SUBCUTANEOUS	Prescription	None	Yes	Yes
MOUNJARO	TIRZEPATIDE	10MG/0.5ML (10MG/0.5ML)	SOLUTION;SUBCUTANEOUS	Prescription	None	Yes	Yes
MOUNJARO	TIRZEPATIDE	12.5MG/0.5ML (12.5MG/0.5ML)	SOLUTION;SUBCUTANEOUS	Prescription	None	Yes	Yes
MOUNJARO	TIRZEPATIDE	15MG/0.5ML (15MG/0.5ML)	SOLUTION;SUBCUTANEOUS	Prescription	None	Yes	Yes

Showing 1 to 6 of 6 entries

Approval Date(s) and History, Letters, Labels, Reviews for NDA 215866

Original Approvals or Tentative Approvals

CSVExcelPrint

Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels, Patient Package Insert	Notes
05/13/2022	ORIG-1	Approval	Type 1 - New Molecular Entity	PRIORITY	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/215866s000lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2022/215866Orig1s000ltr.pdf) Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2022/215866Orig1s000TOC.cfm)	

Showing 1 to 1 of 1 entries

Supplements

CSVExcelPrint

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
07/28/2023	SUPPL-6	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/215866Orig1s002s006lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2023/215866Orig1s002s006ltr.pdf)	
07/28/2023	SUPPL-2	Labeling-Container/Carton Labels, Labeling-Medication Guide, Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/215866Orig1s002s006lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2023/215866Orig1s002s006ltr.pdf)	

Showing 1 to 2 of 2 entries

Labels for NDA 215866

Drugs@FDA: FDA-Approved Drugs

[Home \(index.cfm\)](#) | [Previous Page](#)

New Drug Application (NDA): 215866
Company: ELI LILLY AND CO

-  EMAIL (MAILTO:7SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=215866)
- [Medication Guide \(https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/215866Orig1s002s006lbl.pdf#page=20\)](https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/215866Orig1s002s006lbl.pdf#page=20)

Products on NDA 215866

Approval Date(s) and History, Letters, Labels, Reviews for NDA 215866

Labels for NDA 215866

CSVExcelPrint

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
07/28/2023	SUPPL-6	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/215866Orig1s002s006lbl.pdf)	
07/28/2023	SUPPL-2	Labeling-Container/Carton Labels	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/215866Orig1s002s006lbl.pdf)	
07/28/2023	SUPPL-2	Labeling-Medication Guide	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/215866Orig1s002s006lbl.pdf)	
07/28/2023	SUPPL-2	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/215866Orig1s002s006lbl.pdf)	
05/13/2022	ORIG-1	Approval	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/215866s000lbl.pdf)	

Showing 1 to 5 of 5 entries