Drugs@FDA: FDA-Approved Drugs

New Drug Application (NDA): 209637
Company: NOVO

EMAIL (MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=209637)

- Medication Guide (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/209637s012lbl.pdf#page=27)

Products on NDA 209637

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
OZEMPIC	SEMAGLUTIDE	2MG/1.5ML (1.34MG/ML)	SOLUTION;SUBCUTANEOUS	Prescription	None	Yes	Yes
OZEMPIC	SEMAGLUTIDE	4MG/3ML (1.34MG/ML)	SOLUTION;SUBCUTANEOUS	Prescription	None	Yes	Yes
OZEMPIC	SEMAGLUTIDE	8MG/3ML (2.68MG/ML)	SOLUTION;SUBCUTANEOUS	Prescription	None	Yes	Yes
OZEMPIC	SEMAGLUTIDE	2MG/3ML (0.68MG/ML)	SOLUTION;SUBCUTANEOUS	Prescription	None	Yes	Yes

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Approval Date(s) and History, Letters, Labels, Reviews for NDA 209637

Original Approvals or Tentative Approvals

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Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels, Patient Package Insert	Notes
12/05/2017	ORIG-1	Approval	Type 1 - New Molecular Entity	STANDARD	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209637lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/209637s000ltr.pdf) Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209637Orig1s000TOC.cfm)	

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Supplements

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Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
09/22/2023	SUPPL-21	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209637s020s021lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/209637Orig1s020,s021ltr.pdf)	
09/22/2023	SUPPL-20	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209637s020s021lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/209637Orig1s020,s021ltr.pdf)	
10/06/2022	SUPPL-12	Labeling-Container/Carton Labels, Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/209637s012lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/209637Orig1s012ltr.pdf)	
03/28/2022	SUPPL-9	Efficacy-New Dosing Regimen	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/209637Orig1s009lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/209637Orig1s009ltr.pdf)	
04/12/2021	SUPPL-8	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/209637s008lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2021/209637Orig1s008ltr.pdf)	
01/16/2020	SUPPL-3	Efficacy-New Indication	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/209637s003lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/209637Orig1s003ltr.pdf)	

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
11/27/2019	SUPPL-4	Labeling-Container/Carton Labels, Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/209637s004lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/209637Orig1s004ltr.pdf)**	
04/09/2019	SUPPL-1	Labeling-Container/Carton Labels	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/209637s001lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/209637Orig1s001ltr.pdf)**	

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Labels for NDA 209637

Drugs@FDA: FDA-Approved Drugs

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- Medication Guide (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/209637s012lbl.pdf#page=27)

Products on NDA 209637

Approval Date(s) and History, Letters, Labels, Reviews for NDA 209637

Labels for NDA 209637

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Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
09/22/2023	SUPPL-21	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209637s020s021lbl.pdf)**	
09/22/2023	SUPPL-20	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209637s020s021lbl.pdf)**	
10/06/2022	SUPPL-12	Labeling-Container/Carton Labels	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/209637s012lbl.pdf)**	
10/06/2022	SUPPL-12	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/209637s012lbl.pdf)**	
03/28/2022	SUPPL-9	Efficacy-New Dosing Regimen	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/209637Orig1s009lbl.pdf)**	
04/12/2021	SUPPL-8	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/209637s008lbl.pdf)**	
01/16/2020	SUPPL-3	Efficacy-New Indication	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/209637s003lbl.pdf)**	
11/27/2019	SUPPL-4	Labeling-Container/Carton Labels	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/209637s004lbl.pdf)**	
11/27/2019	SUPPL-4	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/209637s004lbl.pdf)**	
04/09/2019	SUPPL-1	Labeling-Container/Carton Labels	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/209637s001lbl.pdf)**	
12/05/2017	ORIG-1	Approval	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209637lbl.pdf)**	

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