

Drugs@FDA: FDA-Approved Drugs

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New Drug Application (NDA): 022341
Company: NOVO NORDISK INC

EMAIL (MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=022341)

- [Medication Guide \(https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/022341s039lbl.pdf#page=31\)](https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/022341s039lbl.pdf#page=31)

Products on NDA 022341

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
VICTOZA	LIRAGLUTIDE RECOMBINANT	18MG/3ML (6MG/ML)	SOLUTION;SUBCUTANEOUS	Prescription	None	Yes	Yes

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Approval Date(s) and History, Letters, Labels, Reviews for NDA 022341

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
01/25/2010	ORIG-1	Approval	Type 1 - New Molecular Entity	STANDARD	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022341lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2010/022341s000ltr.pdf) Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022341s000TOC.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
07/05/2023	SUPPL-39	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/022341s039lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2023/022341Orig1s039ltr.pdf)	
06/10/2022	SUPPL-38	Labeling-Package Insert, Labeling-Medication Guide	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/022341s037s038lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2022/022341Orig1s037_s038ltr.pdf)	
06/10/2022	SUPPL-37	Labeling-Package Insert	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2022/022341Orig1s037_s038ltr.pdf)	Label is not available on this site.
11/20/2020	SUPPL-36	Labeling-Package Insert, Labeling-Medication Guide	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/022341s036lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2020/022341Orig1s036ltr.pdf)	
08/05/2020	SUPPL-35	Labeling-Package Insert, Labeling-Medication Guide	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/022341s035lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2020/022341Orig1s035ltr.pdf)	
06/17/2019	SUPPL-31	Efficacy-New Patient Population	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/022341s031lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2019/022341Orig1s031ltr.pdf)	

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
08/25/2017	SUPPL-27	Efficacy-New Indication	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/022341s027lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2017/022341Orig1s027ltr.pdf) Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/022341Orig1s027.pdf)	
07/26/2017	SUPPL-29	REMS - MODIFIED - D-N-A	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2017/022341Orig1s029ltr.pdf)	Label is not available on this site.
04/25/2017	SUPPL-28	Labeling-Medication Guide, Labeling-Container/Carton Labels	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/022341s028lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2017/022341Orig1s028ltr.pdf)	
09/20/2016	SUPPL-26	REMS-Modified	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2016/022341Orig1s026ltr.pdf)	Label is not available on this site.
04/22/2016	SUPPL-25	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/022341s025lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2016/022341Orig1s025ltr.pdf)	
07/01/2015	SUPPL-24	REMS-Modified	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2015/022341Orig1s024ltr.pdf)	Label is not available on this site.
03/09/2015	SUPPL-23	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/022341s023lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2015/022341Orig1s023ltr.pdf)	
02/25/2015	SUPPL-22	Labeling-Container/Carton Labels	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/022341s022lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2015/022341Orig1s022ltr.pdf)	
07/31/2014	SUPPL-21	REMS-Modified	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2014/022341Orig1s021ltr.pdf)	Label is not available on this site.
06/13/2013	SUPPL-20	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/022341s020lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2013/022341Orig1s020ltr.pdf)	
04/16/2013	SUPPL-18	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/022341s018lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2013/022341Orig1s018ltr.pdf)	
12/13/2012	SUPPL-17	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/022341s017lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2012/022341Orig1s017ltr.pdf)	
12/03/2012	SUPPL-10	Manufacturing (CMC)		Label is not available on this site.
04/06/2012	SUPPL-13	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/022341s007s009s013lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2012/022341s007,s009,s013ltr.pdf)	
04/06/2012	SUPPL-9	Efficacy-New Indication	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/022341s007s009s013lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2012/022341s007,s009,s013ltr.pdf)	
04/06/2012	SUPPL-7	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/022341s007s009s013lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2012/022341s007,s009,s013ltr.pdf)	
05/18/2011	SUPPL-4	Labeling-Package Insert, REMS-Modified	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022341s004lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2011/022341Orig1s004ltr.pdf)	
12/22/2010	SUPPL-1	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022341s001lbl.pdf)	

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Labels for NDA 022341



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Products on NDA 022341 ▼

Approval Date(s) and History, Letters, Labels, Reviews for NDA 022341 ▼

Labels for NDA 022341 ▲

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Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
07/05/2023	SUPPL-39	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/022341s039lbl.pdf)	
06/10/2022	SUPPL-38	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/022341s037s038lbl.pdf)	
06/10/2022	SUPPL-38	Labeling-Medication Guide	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/022341s037s038lbl.pdf)	
11/20/2020	SUPPL-36	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/022341s036lbl.pdf)	
11/20/2020	SUPPL-36	Labeling-Medication Guide	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/022341s036lbl.pdf)	
08/05/2020	SUPPL-35	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/022341s035lbl.pdf)	
08/05/2020	SUPPL-35	Labeling-Medication Guide	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/022341s035lbl.pdf)	
06/17/2019	SUPPL-31	Efficacy-New Patient Population	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/022341s031lbl.pdf)	
08/25/2017	SUPPL-27	Efficacy-New Indication	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/022341s027lbl.pdf)	
04/25/2017	SUPPL-28	Labeling-Medication Guide	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/022341s028lbl.pdf)	
04/25/2017	SUPPL-28	Labeling-Container/Carton Labels	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/022341s028lbl.pdf)	
04/22/2016	SUPPL-25	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/022341s025lbl.pdf)	
03/09/2015	SUPPL-23	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/022341s023lbl.pdf)	
02/25/2015	SUPPL-22	Labeling-Container/Carton Labels	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/022341s022lbl.pdf)	
06/13/2013	SUPPL-20	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/022341s020lbl.pdf)	

Novo Nordisk Exhibit 0400

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
04/16/2013	SUPPL-18	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/022341s018lbl.pdf)	
12/13/2012	SUPPL-17	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/022341s017lbl.pdf)	
04/06/2012	SUPPL-13	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/022341s007s009s013lbl.pdf)	
04/06/2012	SUPPL-9	Efficacy-New Indication	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/022341s007s009s013lbl.pdf)	
04/06/2012	SUPPL-7	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/022341s007s009s013lbl.pdf)	
05/18/2011	SUPPL-4	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022341s004lbl.pdf)	
05/18/2011	SUPPL-4	REMS-Modified	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022341s004lbl.pdf)	
12/22/2010	SUPPL-1	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022341s001lbl.pdf)	
01/25/2010	ORIG-1	Approval	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022341lbl.pdf)	

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