

# Drugs@FDA: FDA-Approved Drugs

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Biologic License Application (BLA): 208583  
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=208583).

- [Medication Guide \(https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2023/208583s021lbl.pdf#page=42\)](https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/208583s021lbl.pdf#page=42).
- [This Former NDA Was Deemed To Be a BLA on March 23, 2020. \(https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=faq.page#nda\\_bla\)](https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=faq.page#nda_bla).

## Products on BLA 208583

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD
+ XULTOPHY 100/3.6	INSULIN DEGLUDEC; LIRAGLUTIDE	300 UNITS/3ML;10.8MG/3ML (100 UNITS/ML;3.6MG/ML)	SOLUTION;SUBCUTANEOUS	Prescription	None	No

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## Approval Date(s) and History, Letters, Labels, Reviews for BLA 208583

### 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
11/21/2016	ORIG-1	Approval		N/A	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/208583s000lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/208583s000lbl.pdf)</a> <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2016/208583Orig1s000ltr.pdf">Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2016/208583Orig1s000ltr.pdf)</a> <a href="https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=faq.page#nda_bla">Review (https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=faq.page#nda_bla)</a>	

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### Supplements

CSV Excel Print

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
07/10/2023	SUPPL-21	Supplement	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/208583s021lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/208583s021lbl.pdf)</a> <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2023/208583Orig1s021ltr.pdf">Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2023/208583Orig1s021ltr.pdf)</a>	
06/10/2022	SUPPL-19	Supplement	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/208583s018s019lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/208583s018s019lbl.pdf)</a> <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2022/208583Orig1s018, s019ltr.pdf">Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2022/208583Orig1s018, s019ltr.pdf)</a>	
06/10/2022	SUPPL-18	Supplement	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/208583s018s019lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/208583s018s019lbl.pdf)</a> <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2022/208583Orig1s018, s019ltr.pdf">Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2022/208583Orig1s018, s019ltr.pdf)</a>	
11/15/2019	SUPPL-15	Supplement	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208583s014s015lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208583s014s015lbl.pdf)</a> <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2019/208583Orig1s014, s015ltr.pdf">Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2019/208583Orig1s014, s015ltr.pdf)</a>	
11/15/2019	SUPPL-14	Supplement	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208583s014s015lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208583s014s015lbl.pdf)</a> <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2019/208583Orig1s014, s015ltr.pdf">Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2019/208583Orig1s014, s015ltr.pdf)</a>	
08/08/2019	SUPPL-12	Supplement	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208583s012lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208583s012lbl.pdf)</a> <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2019/208583Orig1s012ltr.pdf">Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2019/208583Orig1s012ltr.pdf)</a>	
02/27/2019	SUPPL-11	Supplement	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208583s008s010s011lbl.pdf">Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208583s008s010s011lbl.pdf)</a> <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2019/208583Orig1s008s010s011ltr.pdf">Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2019/208583Orig1s008s010s011ltr.pdf)</a>	

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
02/27/2019	SUPPL-10	Supplement	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208583s008s010s011lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208583s008s010s011lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2019/208583Orig1s008s010s011ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2019/208583Orig1s008s010s011ltr.pdf</a> )	
02/27/2019	SUPPL-8	Supplement	Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2019/208583Orig1s008s010s011ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2019/208583Orig1s008s010s011ltr.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2019/208583Orig1s008s010s011ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2019/208583Orig1s008s010s011ltr.pdf</a> )	Label is not available on this site.
02/01/2019	SUPPL-3	Supplement	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208583s002s003lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208583s002s003lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2019/208583Orig1s002_s003ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2019/208583Orig1s002_s003ltr.pdf</a> )	
02/01/2019	SUPPL-2	Supplement	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208583s002s003lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208583s002s003lbl.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2019/208583Orig1s002_s003ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2019/208583Orig1s002_s003ltr.pdf</a> )	
12/12/2017	SUPPL-1	Supplement	Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2017/208583Orig1s001ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2017/208583Orig1s001ltr.pdf</a> )	Label is not available on this site.

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**Labels for BLA 208583**



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EMAIL (MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=208583).

- [Medication Guide \(https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2023/208583s021lbl.pdf#page=42\)](https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/208583s021lbl.pdf#page=42).
- [This Former NDA Was Deemed To Be a BLA on March 23, 2020. \(https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=faq.page#nda\\_bla\)](https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=faq.page#nda_bla).

Products on BLA 208583

Approval Date(s) and History, Letters, Labels, Reviews for BLA 208583

Labels for BLA 208583

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
07/10/2023	SUPPL-21	Labeling-Package Insert	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/208583s021lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/208583s021lbl.pdf</a> )	
06/10/2022	SUPPL-19	Labeling-Medication Guide	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/208583s018s019lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/208583s018s019lbl.pdf</a> )	
06/10/2022	SUPPL-19	Labeling-Package Insert	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/208583s018s019lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/208583s018s019lbl.pdf</a> )	
06/10/2022	SUPPL-18	Labeling-Container/Carton Labels	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/208583s018s019lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/208583s018s019lbl.pdf</a> )	
06/10/2022	SUPPL-18	Labeling-Medication Guide	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/208583s018s019lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/208583s018s019lbl.pdf</a> )	
06/10/2022	SUPPL-18	Labeling-Package Insert	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/208583s018s019lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/208583s018s019lbl.pdf</a> )	
11/15/2019	SUPPL-15	Labeling-Medication Guide	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208583s014s015lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208583s014s015lbl.pdf</a> )	
11/15/2019	SUPPL-15	Labeling-Package Insert	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208583s014s015lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208583s014s015lbl.pdf</a> )	
11/15/2019	SUPPL-14	Labeling-Container/Carton Labels	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208583s014s015lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208583s014s015lbl.pdf</a> )	
11/15/2019	SUPPL-14	Labeling-Package Insert	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208583s014s015lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208583s014s015lbl.pdf</a> )	
08/08/2019	SUPPL-12	Efficacy-Labeling Change With Clinical Data	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208583s012lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208583s012lbl.pdf</a> )	
02/27/2019	SUPPL-11	Efficacy-New Indication	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208583s008s010s011lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208583s008s010s011lbl.pdf</a> )	
02/27/2019	SUPPL-10	Efficacy-New Indication	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208583s008s010s011lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208583s008s010s011lbl.pdf</a> )	
02/01/2019	SUPPL-3	Efficacy-New Indication	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208583s002s003lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208583s002s003lbl.pdf</a> )	
02/01/2019	SUPPL-2	Efficacy-New Indication	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208583s002s003lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208583s002s003lbl.pdf</a> )	

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
11/21/2016	ORIG-1	Approval	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/208583s000lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/208583s000lbl.pdf</a> )	

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