Drugs@FDA: FDA-Approved Drugs

Biologic License Application (BLA): 208673
Company: SANOFI-AVENTIS US

EMAIL (MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=208673)

- Medication Guide (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/208673s013lbl.pdf#page=29)
- Summary Review (http://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/208673Orig1s000SumR.pdf)
- 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)

Products on BLA 208673

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
SOLIQUA 100/33	INSULIN GLARGINE; LIXISENATIDE	300 UNITS/3ML;99MCG/3ML (100 UNITS/ML;33MCG/ML)	SOLUTION;SUBCUTANEOUS	Prescription	None	No	No

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Approval Date(s) and History, Letters, Labels, Reviews for BLA 208673

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	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/208673s000lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/208673Orig1s000ltr.pdf) Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/208673Orig1_toc.cfm) Summary Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/208673Orig1s000SumR.pdf)	

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Supplements

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Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
09/28/2023	SUPPL-13	Supplement	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/208673s013lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/208673Orig1s013ltr.pdf)	
06/10/2022	SUPPL-12	Supplement	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/208673s012lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/208673Orig1s012ltr.pdf)	
07/28/2021	SUPPL-11	Supplement	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208673s011lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2021/208673Orig1s011ltr.pdf)	
11/15/2019	SUPPL-9	Supplement	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208673s008s009lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/208673Orig1s008, s009ltr.pdf)	
11/15/2019	SUPPL-8	Supplement	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208673s008s009lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/208673Orig1s008, s009ltr.pdf)	
02/27/2019	SUPPL-7	Supplement	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208673s007lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/208673Orig1s007ltr.pdf)	

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
09/28/2017	SUPPL-3	Supplement		Label is not available on this site.
08/29/2017	SUPPL-2	Supplement	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208673s002lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/208673Orig1s002ltr.pdf)**	

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Labels for BLA 208673

Drugs@FDA: FDA-Approved Drugs

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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=208673)

- Medication Guide (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/208673s013lbl.pdf#page=29)
- Summary Review (http://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/208673Orig1s000SumR.pdf)
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Products on BLA 208673

Approval Date(s) and History, Letters, Labels, Reviews for BLA 208673

Labels for BLA 208673

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Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
09/28/2023	SUPPL-13	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/208673s013lbl.pdf)**	
06/10/2022	SUPPL-12	Labeling-Patient Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/208673s012lbl.pdf)**	
06/10/2022	SUPPL-12	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/208673s012lbl.pdf)**	
07/28/2021	SUPPL-11	Labeling-Container/Carton Labels	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208673s011lbl.pdf)**	
07/28/2021	SUPPL-11	Labeling-Medication Guide	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208673s011lbl.pdf)**	
07/28/2021	SUPPL-11	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208673s011lbl.pdf)**	
11/15/2019	SUPPL-9	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208673s008s009lbl.pdf)**	
11/15/2019	SUPPL-9	Labeling-Medication Guide	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208673s008s009lbl.pdf)**	
11/15/2019	SUPPL-8	Labeling-Container/Carton Labels	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208673s008s009lbl.pdf)**	
11/15/2019	SUPPL-8	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208673s008s009lbl.pdf)**	
02/27/2019	SUPPL-7	Efficacy-New Indication	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208673s007lbl.pdf)**	
08/29/2017	SUPPL-2	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208673s002lbl.pdf)**	
11/21/2016	ORIG-1	Approval	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/208673s000lbl.pdf)**	

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