Drugs@FDA: FDA-Approved Drugs

Biologic License Application (BLA): 208471
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=208471)

- Medication Guide (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/208471s007lbl.pdf#page=24)
- 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 208471

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
ADLYXIN	LIXISENATIDE	0.15MG/3ML (0.05MG/ML)	SOLUTION;SUBCUTANEOUS	Prescription	None	No	No
ADLYXIN	LIXISENATIDE	0.3MG/3ML (0.1MG/ML)	SOLUTION;SUBCUTANEOUS	Prescription	None	No	No

Showing 1 to 2 of 2 entries

Approval Date(s) and History, Letters, Labels, Reviews for BLA 208471

Original Approvals or Tentative Approvals

CSV | Excel | Print

Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels, Patient Package Insert	Notes
07/27/2016	ORIG-1	Approval		N/A	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/208471Orig1s000lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/208471Orig1s000ltr.pdf) Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/208471Orig1s000TOC.cfm)	

Showing 1 to 1 of 1 entries

Supplements

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Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
09/28/2023	SUPPL-7	Supplement	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/208471s007lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/208471Orig1s007ltr.pdf)	
06/10/2022	SUPPL-5	Supplement	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/208471s005lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/208471Orig1s005ltr.pdf)	
07/30/2021	SUPPL-4	Supplement	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208471s004lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2021/208471Orig1s004ltr.pdf)	

Showing 1 to 3 of 3 entries

Labels for BLA 208471

Drugs@FDA: FDA-Approved Drugs

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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=208471)

- Medication Guide (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/208471s007lbl.pdf#page=24)
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Products on BLA 208471

Approval Date(s) and History, Letters, Labels, Reviews for BLA 208471

Labels for BLA 208471

CSV | Excel | Print

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
09/28/2023	SUPPL-7	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/208471s007lbl.pdf)**	
06/10/2022	SUPPL-5	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/208471s005lbl.pdf)**	
06/10/2022	SUPPL-5	Labeling-Patient Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/208471s005lbl.pdf)**	
07/30/2021	SUPPL-4	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208471s004lbl.pdf)**	
07/27/2016	ORIG-1	Approval	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/208471Orig1s000lbl.pdf)**	

Showing 1 to 5 of 5 entries