Drugs@FDA: FDA-Approved Drugs

New Drug Application (NDA): 208026
Company: BOEHRINGER INGELHEIM

EMAIL (MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=208026)

- Medication Guide (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/208026s024lbl.pdf#page=22)
- Summary Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/208026Orig1s000SumR.pdf)

Products on NDA 208026

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
JENTADUETO XR	LINAGLIPTIN; METFORMIN HYDROCHLORIDE	2.5MG;1GM	TABLET, EXTENDED RELEASE;ORAL	Prescription	None	Yes	No
JENTADUETO XR	LINAGLIPTIN; METFORMIN HYDROCHLORIDE	5MG;1GM	TABLET, EXTENDED RELEASE;ORAL	Prescription	None	Yes	Yes

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Approval Date(s) and History, Letters, Labels, Reviews for NDA 208026

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
05/27/2016	ORIG-1	Approval	Type 4 - New Combination	STANDARD	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/208026s000lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/208026Orig1s000ltr.pdf) Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/208026Orig1s000TOC.cfm) Summary Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/208026Orig1s000SumR.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
06/20/2023	SUPPL-24	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/201281s035,208026s024lbl.pdf#page=24) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/201281Orig1s035;208026Orig1s024ltr.pdf)	
10/01/2021	SUPPL-20	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208026s020lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2021/208026Orig1s020ltr.pdf)	
03/30/2020	SUPPL-12	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/208026s012lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/201280Orig1s020, 201281Orig1s024, 206073Orig1s021, 208026Orig1s012ltr.pdf)	
07/03/2019	SUPPL-8	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208026s008lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/201280Orig1s018, 201281Orig1s022, 206073Orig1s017, 208026Orig1s008ltr.pdf)	
07/01/2019	SUPPL-13	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208026s013lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/201280Orig1s021, 201281Orig1s025, 206073Orig1s022, 208026Orig1s013ltr.pdf)	

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
08/10/2017	SUPPL-5	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208026s005lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/201280Orig1s016,201281Orig1s019,208026Orig1s005,206073Orig1s013ltr.pdf)**	
03/14/2017	SUPPL-3	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208026s003lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/201280Orig1s014,201281Orig1s017,206073Orig1s008,208026Orig1s003ltr.pdf)**	
12/23/2016	SUPPL-4	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/208026s004lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/201280Orig1s015,208026Orig1s004ltr.pdf)**	

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Labels for NDA 208026

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Products on NDA 208026

Approval Date(s) and History, Letters, Labels, Reviews for NDA 208026

Labels for NDA 208026

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Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
06/20/2023	SUPPL-24	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/201281s035,208026s024lbl.pdf#page=24)**	
10/01/2021	SUPPL-20	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208026s020lbl.pdf)**	
03/30/2020	SUPPL-12	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/208026s012lbl.pdf)**	
07/03/2019	SUPPL-8	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208026s008lbl.pdf)**	
07/01/2019	SUPPL-13	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208026s013lbl.pdf)**	
08/10/2017	SUPPL-5	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208026s005lbl.pdf)**	
03/14/2017	SUPPL-3	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208026s003lbl.pdf)**	
12/23/2016	SUPPL-4	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/208026s004lbl.pdf)**	
05/27/2016	ORIG-1	Approval	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/208026s000lbl.pdf)**	

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