Drugs@FDA: FDA-Approved Drugs

New Drug Application (NDA): 201281
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=201281)

- Medication Guide (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/201281s035lbl.pdf#page=21)
- Summary Review (http://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/201281Orig1s000SumR.pdf)

Products on NDA 201281

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
JENTADUETO	LINAGLIPTIN; METFORMIN HYDROCHLORIDE	2.5MG;500MG	TABLET;ORAL	Prescription	AB	Yes	No
JENTADUETO	LINAGLIPTIN; METFORMIN HYDROCHLORIDE	2.5MG;850MG	TABLET;ORAL	Prescription	AB	Yes	No
JENTADUETO	LINAGLIPTIN; METFORMIN HYDROCHLORIDE	2.5MG;1GM	TABLET;ORAL	Prescription	AB	Yes	Yes

Showing 1 to 3 of 3 entries

Approval Date(s) and History, Letters, Labels, Reviews for NDA 201281

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
01/30/2012	ORIG-1	Approval	Type 4 - New Combination	STANDARD	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/201281s000lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2012/201281s000ltr.pdf) Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/201281_linagliptin_toc.cfm) Summary Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/201281Orig1s000SumR.pdf)	

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
06/20/2023	SUPPL-35	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/201281s035lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/201281Orig1s035;208026Orig1s024ltr.pdf)	
04/15/2022	SUPPL-31	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/201281s031lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/201280Orig1s025; 201281Orig1s031ltr.pdf)	
03/30/2020	SUPPL-24	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/201281s024lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/201280Orig1s020, 201281Orig1s024, 206073Orig1s021, 208026Orig1s012ltr.pdf)	
07/03/2019	SUPPL-22	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/201281s022lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/201280Orig1s018, 201281Orig1s022, 206073Orig1s017, 208026Orig1s008ltr.pdf)	

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
07/01/2019	SUPPL-25	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/201281s025lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/201280Orig1s021, 201281Orig1s025, 206073Orig1s022, 208026Orig1s013ltr.pdf)**	
08/10/2017	SUPPL-19	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/201281s019lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/201280Orig1s016,201281Orig1s019,208026Orig1s005,206073Orig1s013ltr.pdf)**	
03/14/2017	SUPPL-17	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/201281s017lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/201280Orig1s014,201281Orig1s017,206073Orig1s008,208026Orig1s003ltr.pdf)**	
12/23/2016	SUPPL-18	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/201281S014S018lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/201281Orig1s014,s018ltr.pdf)**	
12/23/2016	SUPPL-14	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/201281S014S018lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/201281Orig1s014,s018ltr.pdf)**	
04/29/2016	SUPPL-12	Manufacturing (CMC)		Label is not available on this site.
02/11/2016	SUPPL-11	Manufacturing (CMC)		Label is not available on this site.
09/18/2015	SUPPL-9	Manufacturing (CMC)		Label is not available on this site.
08/28/2015	SUPPL-10	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/201281s010lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/201280Orig1s012,201281s010,206073Orig1s001ltr.pdf)**	
07/28/2015	SUPPL-8	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/201281s008lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/201280Orig1s011,201281Orig1s008ltr.pdf)**	
07/30/2014	SUPPL-6	Efficacy-New Dosing Regimen	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/201281s006lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/201281Orig1s006ltr.pdf)**	
05/22/2014	SUPPL-7	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/201281s007lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/201280Orig1s009,201281Orig1s007ltr.pdf)**	
12/18/2013	SUPPL-5	Manufacturing (CMC)		Label is not available on this site.
09/05/2013	SUPPL-4	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/201281s004lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2013/201281Orig1s004ltr.pdf)**	
06/18/2013	SUPPL-3	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/201281s003lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2013/201281Orig1s003ltr.pdf)**	
09/25/2012	SUPPL-2	Labeling-Container/Carton Labels	**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2012/201281Orig1s002ltr.pdf)**	Label is not available on this site.

Showing 1 to 20 of 20 entries

Labels for NDA 201281

Therapeutic Equivalents for NDA 201281

Drugs@FDA: FDA-Approved Drugs

New Drug Application (NDA): 201281
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=201281)

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Products on NDA 201281

Approval Date(s) and History, Letters, Labels, Reviews for NDA 201281

Labels for NDA 201281

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Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
06/20/2023	SUPPL-35	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/201281s035lbl.pdf)**	
04/15/2022	SUPPL-31	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/201281s031lbl.pdf)**	
03/30/2020	SUPPL-24	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/201281s024lbl.pdf)**	
07/03/2019	SUPPL-22	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/201281s022lbl.pdf)**	
07/01/2019	SUPPL-25	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/201281s025lbl.pdf)**	
08/10/2017	SUPPL-19	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/201281s019lbl.pdf)**	
03/14/2017	SUPPL-17	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/201281s017lbl.pdf)**	
12/23/2016	SUPPL-18	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/201281S014S018lbl.pdf)**	
12/23/2016	SUPPL-14	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/201281S014S018lbl.pdf)**	
08/28/2015	SUPPL-10	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/201281s010lbl.pdf)**	
07/28/2015	SUPPL-8	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/201281s008lbl.pdf)**	
07/30/2014	SUPPL-6	Efficacy-New Dosing Regimen	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/201281s006lbl.pdf)**	
05/22/2014	SUPPL-7	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/201281s007lbl.pdf)**	
09/05/2013	SUPPL-4	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/201281s004lbl.pdf)**	

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
06/18/2013	SUPPL-3	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/201281s003lbl.pdf)**	
01/30/2012	ORIG-1	Approval	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/201281s000lbl.pdf)**	

Showing 1 to 16 of 16 entries

Therapeutic Equivalents for NDA 201281

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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=201281)

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Products on NDA 201281

Approval Date(s) and History, Letters, Labels, Reviews for NDA 201281

Labels for NDA 201281

Therapeutic Equivalents for NDA 201281

JENTADUETO

TABLET;ORAL; 2.5MG;500MG
TE Code = AB

CSV Excel Print

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code	Application No.	Company
JENTADUETO	**LINAGLIPTIN; METFORMIN HYDROCHLORIDE**	**2.5MG;500MG**	**TABLET;ORAL**	**Prescription**	**Yes**	**AB**	**201281**	**BOEHRINGER INGELHEIM**
LINAGLIPTIN AND METFORMIN HYDROCHLORIDE	LINAGLIPTIN; METFORMIN HYDROCHLORIDE	2.5MG;500MG	TABLET;ORAL	Prescription	No	AB	208336 (/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=208336)	SUNSHINE

Showing 1 to 2 of 2 entries

TABLET;ORAL; 2.5MG;850MG
TE Code = AB

CSV Excel Print

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code	Application No.	Company
JENTADUETO	**LINAGLIPTIN; METFORMIN HYDROCHLORIDE**	**2.5MG;850MG**	**TABLET;ORAL**	**Prescription**	**Yes**	**AB**	**201281**	**BOEHRINGER INGELHEIM**
LINAGLIPTIN AND METFORMIN HYDROCHLORIDE	LINAGLIPTIN; METFORMIN HYDROCHLORIDE	2.5MG;850MG	TABLET;ORAL	Prescription	No	AB	208336 (/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=208336)	SUNSHINE

Showing 1 to 2 of 2 entries

TABLET;ORAL; 2.5MG;1GM
TE Code = AB

CSV Excel Print

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code	Application No.	Company
JENTADUETO	**LINAGLIPTIN; METFORMIN HYDROCHLORIDE**	**2.5MG;1GM**	**TABLET;ORAL**	**Prescription**	**Yes**	**AB**	**201281**	**BOEHRINGER INGELHEIM**
LINAGLIPTIN AND METFORMIN HYDROCHLORIDE	LINAGLIPTIN; METFORMIN HYDROCHLORIDE	2.5MG;1GM	TABLET;ORAL	Prescription	No	AB	208336 (/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=208336)	SUNSHINE

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