

Drugs@FDA: FDA-Approved Drugs

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New Drug Application (NDA): 204629
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=204629).

- [Medication Guide \(https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/204629s040lbl.pdf#page=47\)](https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/204629s040lbl.pdf#page=47)
- [Summary Review \(http://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/204629Orig1s000SumR.pdf\)](http://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/204629Orig1s000SumR.pdf)

Products on NDA 204629

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
JARDIANCE	EMPAGLIFLOZIN	10MG	TABLET;ORAL	Prescription	AB	Yes	No
JARDIANCE	EMPAGLIFLOZIN	25MG	TABLET;ORAL	Prescription	AB	Yes	Yes

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Approval Date(s) and History, Letters, Labels, Reviews for NDA 204629

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
08/01/2014	ORIG-1	Approval	Type 1 - New Molecular Entity	STANDARD	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/204629s000lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2014/204629Orig1s000ltr.pdf) Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/204629Orig1s000TOC.cfm) Summary Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/204629Orig1s000SumR.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
09/21/2023	SUPPL-40	Efficacy-New Indication	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/204629s040lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2023/204629Orig1s040ltr.pdf)	
09/12/2023	SUPPL-41	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/204629s041lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2023/204629Orig1s041ltr.pdf)	
06/20/2023	SUPPL-42	Efficacy-New Patient Population	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/204629s042lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2023/204629Orig1s042ltr.pdf)	
10/13/2022	SUPPL-39	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/204629s039lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2022/204629Orig1s039;2060730rig1s033;206111Orig1s036;2086580rig1s023ltr.pdf)	
03/21/2022	SUPPL-34	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/204629s034lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2022/204629Orig1s034;2060730rig1s031;206111Orig1s031;2086580rig1s017ltr.pdf)	

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
02/24/2022	SUPPL-33	Efficacy-New Indication	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/204629s033lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2022/204629Orig1s033ltr.pdf) Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/204629Orig1s033.pdf)	
08/18/2021	SUPPL-26	Efficacy-New Indication	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/204629s026lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2021/204629Orig1s026ltr.pdf)	
06/11/2021	SUPPL-29	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/204629s028s029lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2021/204629Orig1s028_s029;206073Orig1s027_s030;206111Orig1s025_s026;208658Orig1s013_s015;212614Orig1s008_s010ltr.pdf)	
06/11/2021	SUPPL-28	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/204629s028s029lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2021/204629Orig1s028_206073Orig1s027_206111Orig1s025_208658Orig1s013_212614Orig1s008ltr.pdf)	
01/24/2020	SUPPL-23	Labeling-Medication Guide, Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/204629s023lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2020/204629Orig1s023_206073Orig1s023_206111Orig1s022_208658Orig1s009ltr.pdf)	
12/21/2018	SUPPL-19	Labeling-Container/ Carton Labels	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/204629s019lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2018/204629Orig1s019ltr.pdf)	
10/26/2018	SUPPL-18	Labeling-Package Insert, Labeling-Medication Guide	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/204629s018lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2018/204629Orig1s018_206073Orig1s019_206111Orig1s018_208658Orig1s006ltr.pdf)	
12/13/2017	SUPPL-16	Labeling-Patient Package Insert, Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/204629s016lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2017/204629Orig1s016ltr.pdf)	
12/02/2016	SUPPL-8	Efficacy-New Indication	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/204629s008lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2016/204629Orig1s008ltr.pdf) Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2021/204629Orig1s008.pdf)	
07/08/2016	SUPPL-12	Labeling-Patient Package Insert, Labeling-Package Insert	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2016/204629Orig1s012ltr.pdf)	Label is not available on this site.
04/15/2016	SUPPL-11	Manufacturing (CMC)		Label is not available on this site.
03/18/2016	SUPPL-5	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/204629s005lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2016/204629Orig1s005ltr.pdf) Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2021/204629Orig1s005.pdf)	
02/05/2016	SUPPL-4	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/204629s004lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2016/204629Orig1s004ltr.pdf)	
01/21/2016	SUPPL-10	Manufacturing (CMC)		Label is not available on this site.
01/12/2016	SUPPL-9	Manufacturing (CMC)		Label is not available on this site.
12/04/2015	SUPPL-7	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/204629s007lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2015/204629Orig1s007ltr.pdf) Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2021/204629Orig1s007.pdf)	
06/26/2015	SUPPL-3	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/204629s001s002s003lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2015/204629Orig1s001_s002_s003ltr.pdf) Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2021/204629Orig1s003.pdf)	

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
06/26/2015	SUPPL-2	Efficacy-Labeling Change With Clinical Data	<p>Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/204629s001s002s003lbl.pdf)</p> <p>Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2015/204629Orig1s001,s002,s003ltr.pdf)</p> <p>Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2021/204629Orig1s002.pdf)</p>	
06/26/2015	SUPPL-1	Efficacy-Labeling Change With Clinical Data	<p>Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/204629s001s002s003lbl.pdf)</p> <p>Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2015/204629Orig1s001,s002,s003ltr.pdf)</p> <p>Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2021/204629Orig1s001.pdf)</p>	

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Labels for NDA 204629 ▼

Therapeutic Equivalents for NDA 204629 ▼

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- [Medication Guide \(https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/204629s040lbl.pdf#page=47\)](https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/204629s040lbl.pdf#page=47).
- [Summary Review \(http://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/204629Orig1s000SumR.pdf\)](http://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/204629Orig1s000SumR.pdf).

Products on NDA 204629 ▼

Approval Date(s) and History, Letters, Labels, Reviews for NDA 204629 ▼

Labels for NDA 204629 ▲

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Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note	
09/21/2023	SUPPL-40	Efficacy-New Indication	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/204629s040lbl.pdf)		
09/12/2023	SUPPL-41	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/204629s041lbl.pdf)		
06/20/2023	SUPPL-42	Efficacy-New Patient Population	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/204629s042lbl.pdf)		
10/13/2022	SUPPL-39	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/204629s039lbl.pdf)		
03/21/2022	SUPPL-34	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/204629s034lbl.pdf)		
02/24/2022	SUPPL-33	Efficacy-New Indication	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/204629s033lbl.pdf)		
08/18/2021	SUPPL-26	Efficacy-New Indication	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/204629s026lbl.pdf)		
06/11/2021	SUPPL-29	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/204629s028s029lbl.pdf)		
06/11/2021	SUPPL-28	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/204629s028s029lbl.pdf)		
01/24/2020	SUPPL-23	Labeling-Medication Guide	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/204629s023lbl.pdf)		
01/24/2020	SUPPL-23	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/204629s023lbl.pdf)		
12/21/2018	SUPPL-19	Labeling-Container/Carton Labels	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/204629s019lbl.pdf)		
10/26/2018	SUPPL-18	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/204629s018lbl.pdf)		
10/26/2018	SUPPL-18	Labeling-Medication Guide	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/204629s018lbl.pdf)		
12/13/2017	SUPPL-16	Labeling-Patient Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/204629s016lbl.pdf)		
12/13/2017	SUPPL-16	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/204629s016lbl.pdf)		

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
12/02/2016	SUPPL-8	Efficacy-New Indication	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/204629s008lbl.pdf)	
03/18/2016	SUPPL-5	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/204629s005lbl.pdf)	
02/05/2016	SUPPL-4	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/204629s004lbl.pdf)	
12/04/2015	SUPPL-7	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/204629s007lbl.pdf)	
06/26/2015	SUPPL-3	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/204629s001s002s003lbl.pdf)	
06/26/2015	SUPPL-2	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/204629s001s002s003lbl.pdf)	
06/26/2015	SUPPL-1	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/204629s001s002s003lbl.pdf)	
08/01/2014	ORIG-1	Approval	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/204629s000lbl.pdf)	

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