

Drugs@FDA: FDA-Approved Drugs

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New Drug Application (NDA): 204042
Company: JANSSEN PHARMS

EMAIL (MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=204042)

- [Medication Guide \(https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/204042s040lbl.pdf#page=47\)](https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/204042s040lbl.pdf#page=47)
- [Summary Review \(http://www.accessdata.fda.gov/drugsatfda_docs/NDA/2013/204042Orig1s000SumR.pdf\)](http://www.accessdata.fda.gov/drugsatfda_docs/NDA/2013/204042Orig1s000SumR.pdf)

Products on NDA 204042

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
INVOKANA	CANAGLIFLOZIN	100MG	TABLET;ORAL	Prescription	None	Yes	No
INVOKANA	CANAGLIFLOZIN	300MG	TABLET;ORAL	Prescription	None	Yes	Yes

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Approval Date(s) and History, Letters, Labels, Reviews for NDA 204042

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
03/29/2013	ORIG-1	Approval	Type 1 - New Molecular Entity	STANDARD	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204042s000lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2013/204042Orig1s000ltr.pdf) Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/204042Orig1s000TOC.cfm) Summary Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/NDA/2013/204042Orig1s000SumR.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
07/05/2023	SUPPL-40	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/204042s040lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2023/204042Orig1s040ltr.pdf)	
10/13/2022	SUPPL-39	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/204042s039lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2022/204042Orig1s039,204353Orig1s041,205879Orig1s018ltr.pdf)	
08/18/2020	SUPPL-34	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/204042s034lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2020/204042Orig1s034ltr.pdf)	
01/24/2020	SUPPL-36	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/204042s036lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2020/204042Orig1s036,204353Orig1s036,205879Orig1s014ltr.pdf)	
09/27/2019	SUPPL-32	Efficacy-New Indication	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/204042s032lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2019/204042Orig1s032ltr.pdf) Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/204042Orig1s032TOC.cfm)	
10/29/2018	SUPPL-27	Efficacy-New Indication	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/204042s027lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2018/204042Orig1s027ltr.pdf) Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2021/204042Orig1s027.pdf)	

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
10/26/2018	SUPPL-31	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/204042s031lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2018/204042Orig1s031ltr.pdf)	
07/25/2017	SUPPL-26	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/204042s026lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2017/204042Orig1s026ltr.pdf) Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/204042Orig1s026.pdf)	
02/01/2017	SUPPL-18	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/204042s018lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2017/204042Orig1s018ltr.pdf)	
08/17/2016	SUPPL-22	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/204042s022lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2016/204042Orig1s022ltr.pdf)	
06/16/2016	SUPPL-16	Manufacturing (CMC)		Label is not available on this site.
05/20/2016	SUPPL-19	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/204042s015s019lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2016/204042Orig1s015,s019ltr.pdf)	
05/20/2016	SUPPL-15	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/204042s015s019lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2016/204042Orig1s015,s019ltr.pdf)	
03/28/2016	SUPPL-11	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/204042s011lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2016/204042Orig1s011ltr.pdf)	
03/08/2016	SUPPL-12	Manufacturing (CMC)		Label is not available on this site.
12/04/2015	SUPPL-13	Labeling-Medication Guide	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/204042s013lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2015/204042Orig1s013ltr.pdf) Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/204042Orig1s013.pdf)	
09/10/2015	SUPPL-6	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/204042s006lbl.pdf)	
09/09/2015	SUPPL-9	Manufacturing (CMC)		Label is not available on this site.
03/03/2015	SUPPL-5	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/204042s005lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2015/204042Orig1s005ltr.pdf)	
06/05/2014	SUPPL-3	Manufacturing (CMC)		Label is not available on this site.
05/15/2014	SUPPL-2	Labeling-Medication Guide, Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/204042s002lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2014/204042Orig1s002ltr.pdf)	
11/26/2013	SUPPL-1	Manufacturing (CMC)		Label is not available on this site.

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Labels for NDA 204042



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- [Summary Review \(http://www.accessdata.fda.gov/drugsatfda_docs/NDA/2013/204042Orig1s000SumR.pdf\)](http://www.accessdata.fda.gov/drugsatfda_docs/NDA/2013/204042Orig1s000SumR.pdf)

Products on NDA 204042 ▼

Approval Date(s) and History, Letters, Labels, Reviews for NDA 204042 ▼

Labels for NDA 204042 ▲

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Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
07/05/2023	SUPPL-40	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/204042s040lbl.pdf)	
10/13/2022	SUPPL-39	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/204042s039lbl.pdf)	
08/18/2020	SUPPL-34	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/204042s034lbl.pdf)	
01/24/2020	SUPPL-36	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/204042s036lbl.pdf)	
09/27/2019	SUPPL-32	Efficacy-New Indication	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/204042s032lbl.pdf)	
10/29/2018	SUPPL-27	Efficacy-New Indication	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/204042s027lbl.pdf)	
10/26/2018	SUPPL-31	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/204042s031lbl.pdf)	
07/25/2017	SUPPL-26	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/204042s026lbl.pdf)	
02/01/2017	SUPPL-18	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/204042s018lbl.pdf)	
08/17/2016	SUPPL-22	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/204042s022lbl.pdf)	
05/20/2016	SUPPL-19	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/204042s015s019lbl.pdf)	
05/20/2016	SUPPL-15	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/204042s015s019lbl.pdf)	
03/28/2016	SUPPL-11	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/204042s011lbl.pdf)	
12/04/2015	SUPPL-13	Labeling-Medication Guide	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/204042s013lbl.pdf)	

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09/10/2015	SUPPL-6	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/204042s006lbl.pdf)	
03/03/2015	SUPPL-5	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/204042s005lbl.pdf)	
05/15/2014	SUPPL-2	Labeling-Medication Guide	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/204042s002lbl.pdf)	
05/15/2014	SUPPL-2	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/204042s002lbl.pdf)	
03/29/2013	ORIG-1	Approval	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204042s000lbl.pdf)	

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