Drugs@FDA: FDA-Approved Drugs

New Drug Application (NDA): 205879
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=205879)

- Medication Guide (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/204353s042,205879s019lbl.pdf#page=56)

Products on NDA 205879

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
INVOKAMET XR	CANAGLIFLOZIN; METFORMIN HYDROCHLORIDE	50MG;500MG	TABLET, EXTENDED RELEASE;ORAL	Prescription	None	Yes	No
INVOKAMET XR	CANAGLIFLOZIN; METFORMIN HYDROCHLORIDE	50MG;1GM	TABLET, EXTENDED RELEASE;ORAL	Prescription	None	Yes	No
INVOKAMET XR	CANAGLIFLOZIN; METFORMIN HYDROCHLORIDE	150MG;500MG	TABLET, EXTENDED RELEASE;ORAL	Prescription	None	Yes	No
INVOKAMET XR	CANAGLIFLOZIN; METFORMIN HYDROCHLORIDE	150MG;1GM	TABLET, EXTENDED RELEASE;ORAL	Prescription	None	Yes	Yes

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Approval Date(s) and History, Letters, Labels, Reviews for NDA 205879

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
09/20/2016	ORIG-1	Approval	Type 4 - New Combination	STANDARD	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/205879s000lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/205879Orig1s000ltr.pdf) Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/205879Orig1s000TOC.cfm)	

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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-19	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/204353s042,205879s019lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/204353Orig1s042;205879Orig1s019ltr.pdf)	
10/13/2022	SUPPL-18	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/204353s041,205879s018lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/204042Orig1s039,204353Orig1s041,205879Orig1s018ltr.pdf)	
08/18/2020	SUPPL-17	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/204353s039,205879s017lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/204353Orig1s039,205879Orig1s017ltr.pdf)	
01/27/2020	SUPPL-11	Efficacy-New Indication	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/204353s033,205879s011lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/204353Orig1s033,%20205879Orig1s011ltr.pdf)	
01/24/2020	SUPPL-14	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/204353s036,205879s014lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/204042Orig1s036, 204353Orig1s036, 205879Orig1s014ltr.pdf)	
10/29/2018	SUPPL-7	Efficacy-New Indication	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/204353s025,205879s007lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2018/204353Orig1s025,205879Orig1s007ltr.pdf)	

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
10/26/2018	SUPPL-9	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/205879s009lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2018/204353Orig1s031,205879Orig1s009ltr.pdf)**	
01/02/2018	SUPPL-2	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/205879s002lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2018/205879s002ltr.pdf)**	
08/11/2017	SUPPL-6	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/205879s006lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/205879Orig1s006ltr.pdf)**	
07/25/2017	SUPPL-5	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/205879s005lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/205879Orig1s005ltr.pdf)**	

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Labels for NDA 205879

Drugs@FDA: FDA-Approved Drugs

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07/05/2023	SUPPL-19	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/204353s042,205879s019lbl.pdf)**	
10/13/2022	SUPPL-18	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/204353s041,205879s018lbl.pdf)**	
08/18/2020	SUPPL-17	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/204353s039,205879s017lbl.pdf)**	
01/27/2020	SUPPL-11	Efficacy-New Indication	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/204353s033,205879s011lbl.pdf)**	
01/24/2020	SUPPL-14	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/204353s036,205879s014lbl.pdf)**	
10/29/2018	SUPPL-7	Efficacy-New Indication	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/204353s025,205879s007lbl.pdf)**	
10/26/2018	SUPPL-9	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/205879s009lbl.pdf)**	
01/02/2018	SUPPL-2	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/205879s002lbl.pdf)**	
08/11/2017	SUPPL-6	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/205879s006lbl.pdf)**	
07/25/2017	SUPPL-5	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/205879s005lbl.pdf)**	
09/20/2016	ORIG-1	Approval	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/205879s000lbl.pdf)**	

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