Drugs@FDA: FDA-Approved Drugs

New Drug Application (NDA): 209091
Company: ASTRAZENECA AB

EMAIL (MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=209091)

- Medication Guide (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209091s008lbl.pdf#page=37)

Products on NDA 209091

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
QTERN	DAPAGLIFLOZIN; SAXAGLIPTIN HYDROCHLORIDE	10MG;EQ 5MG BASE	TABLET;ORAL	Prescription	None	Yes	Yes
QTERN	DAPAGLIFLOZIN; SAXAGLIPTIN HYDROCHLORIDE	5MG;EQ 5MG BASE	TABLET;ORAL	Prescription	None	Yes	No

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Approval Date(s) and History, Letters, Labels, Reviews for NDA 209091

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
02/27/2017	ORIG-1	Approval	Type 4 - New Combination	STANDARD	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209091s000lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/209091Orig1s000ltr.pdf) Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209091Orig1s000TOC.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
09/12/2023	SUPPL-8	Labeling-Package Insert, Labeling-Patient Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209091s008lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/209091Orig1s008ltr.pdf)	
10/13/2022	SUPPL-7	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/209091s007lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/209091Orig1s007ltr.pdf)	
03/04/2022	SUPPL-6	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/209091s006lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/209091Orig1s006ltr.pdf)	
01/24/2020	SUPPL-5	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/209091s005lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/202293Orig1s021, 205649Orig1s013, 209091Orig1s005, 210874Orig1s003ltr.pdf)	
07/01/2019	SUPPL-4	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/209091s004lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/022350Orig1s023, 200678Orig1s024, 209091Orig1s004, 210874Orig1s001ltr.pdf)	
05/02/2019	SUPPL-2	Efficacy-New Indication	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/209091s002lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/209091Orig1s002ltr.pdf)	

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
10/26/2018	SUPPL-3	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/209091s003lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2018/202293Orig1s017,205649Origs010,209091Orig1s003ltr.pdf)**	

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Labels for NDA 209091

Drugs@FDA: FDA-Approved Drugs

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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=209091)

- Medication Guide (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209091s008lbl.pdf#page=37)

Products on NDA 209091

Approval Date(s) and History, Letters, Labels, Reviews for NDA 209091

Labels for NDA 209091

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Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
09/12/2023	SUPPL-8	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209091s008lbl.pdf)**	
09/12/2023	SUPPL-8	Labeling-Patient Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209091s008lbl.pdf)**	
10/13/2022	SUPPL-7	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/209091s007lbl.pdf)**	
03/04/2022	SUPPL-6	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/209091s006lbl.pdf)**	
01/24/2020	SUPPL-5	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/209091s005lbl.pdf)**	
07/01/2019	SUPPL-4	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/209091s004lbl.pdf)**	
05/02/2019	SUPPL-2	Efficacy-New Indication	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/209091s002lbl.pdf)**	
10/26/2018	SUPPL-3	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/209091s003lbl.pdf)**	
02/27/2017	ORIG-1	Approval	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209091s000lbl.pdf)**	

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