Drugs@FDA: FDA-Approved Drugs

New Drug Application (NDA): 202293
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=202293)

- Medication Guide (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/202293s030lbl.pdf#page=53)
- Summary Review (http://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/202293Orig1s000SumR.pdf)

Products on NDA 202293

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
FARXIGA	DAPAGLIFLOZIN	5MG	TABLET;ORAL	Prescription	AB	Yes	No
FARXIGA	DAPAGLIFLOZIN	10MG	TABLET;ORAL	Prescription	AB	Yes	Yes

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Approval Date(s) and History, Letters, Labels, Reviews for NDA 202293

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
01/08/2014	ORIG-1	Approval	Type 1 - New Molecular Entity	STANDARD	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/202293s000lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/202293Orig1s000ltr.pdf) Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/202293Orig1s000TOC.cfm) Summary Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/202293Orig1s000SumR.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
09/12/2023	SUPPL-30	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/202293s030lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/202293Orig1s030;205649Orig1s021ltr.pdf)	
05/08/2023	SUPPL-26	Efficacy-New Indication	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/202293s026lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/202293Orig1s026ltr.pdf) Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/202293Orig1s026.pdf)	
02/17/2023	SUPPL-27	Labeling-Package Insert, Labeling-Container/Carton Labels	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/202293Orig1s027lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/202293Orig1s027ltr.pdf)	
10/13/2022	SUPPL-28	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/202293s028lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/202293Orig1s028,205649Orig1s018ltr.pdf)	
04/30/2021	SUPPL-24	Efficacy-New Indication	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/202293s024lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2021/202293Orig1s024ltr.pdf) Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2021/202293Orig1s024TOC.cfm)	

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
05/05/2020	SUPPL-20	Efficacy-New Indication	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/202293s020lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/202293Orig1s020ltr.pdf)** **Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2021/202293Orig1s020.pdf)**	
02/03/2020	SUPPL-22	Labeling-Medication Guide, Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/202293Orig1s022lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/202293Orig1s022, 205649Orig1s014ltr.pdf)**	
01/24/2020	SUPPL-21	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/202293s021lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/202293Orig1s021, 205649Orig1s013, 209091Orig1s005, 210874Orig1s003ltr.pdf)**	
10/18/2019	SUPPL-18	Efficacy-New Indication	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/202293s018lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/202293Orig1s018, 205649Orig1s011ltr.pdf)** **Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2021/202293Orig1s018.pdf)**	
02/22/2019	SUPPL-15	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/202293s015lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/202293Orig1s015, 205649Orig1s009ltr.pdf)**	
10/26/2018	SUPPL-17	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/202293s017lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2018/202293Orig1s017,205649Origs010,209091Orig1s003ltr.pdf)**	
10/20/2017	SUPPL-12	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/202293s012lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/202293Orig1s012ltr.pdf)**	
03/01/2017	SUPPL-11	Labeling-Package Insert, Labeling-Medication Guide	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/202293s011lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/202293Orig1s011ltr.pdf)**	
08/17/2016	SUPPL-10	Labeling-Medication Guide, Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/202293s010lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/202293Orig1s010ltr.pdf)**	
06/14/2016	SUPPL-9	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/202293s009lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/202293Orig1s009ltr.pdf)**	
01/12/2016	SUPPL-6	Manufacturing (CMC)		Label is not available on this site.
01/06/2016	SUPPL-7	Manufacturing (CMC)		Label is not available on this site.
12/04/2015	SUPPL-8	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/202293s008lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/202293Orig1s008ltr.pdf)**	
03/11/2015	SUPPL-2	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/202293s002lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/202293Orig1s002ltr.pdf)**	
08/08/2014	SUPPL-3	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/202293s003lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/202293Orig1s003ltr.pdf)**	
07/31/2014	SUPPL-1	Manufacturing (CMC)		Label is not available on this site.

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Labels for NDA 202293

Therapeutic Equivalents for NDA 202293

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=202293)

- Medication Guide (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/202293s030lbl.pdf#page=53)
- Summary Review (http://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/202293Orig1s000SumR.pdf)

Products on NDA 202293

Approval Date(s) and History, Letters, Labels, Reviews for NDA 202293

Labels for NDA 202293

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Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
09/12/2023	SUPPL-30	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/202293s030lbl.pdf)**	
05/08/2023	SUPPL-26	Efficacy-New Indication	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/202293s026lbl.pdf)**	
02/17/2023	SUPPL-27	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/202293Orig1s027lbl.pdf)**	
02/17/2023	SUPPL-27	Labeling-Container/Carton Labels	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/202293Orig1s027lbl.pdf)**	
10/13/2022	SUPPL-28	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/202293s028lbl.pdf)**	
04/30/2021	SUPPL-24	Efficacy-New Indication	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/202293s024lbl.pdf)**	
05/05/2020	SUPPL-20	Efficacy-New Indication	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/202293s020lbl.pdf)**	
02/03/2020	SUPPL-22	Labeling-Medication Guide	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/202293Orig1s022lbl.pdf)**	
02/03/2020	SUPPL-22	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/202293Orig1s022lbl.pdf)**	
01/24/2020	SUPPL-21	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/202293s021lbl.pdf)**	
10/18/2019	SUPPL-18	Efficacy-New Indication	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/202293s018lbl.pdf)**	
02/22/2019	SUPPL-15	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/202293s015lbl.pdf)**	
10/26/2018	SUPPL-17	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/202293s017lbl.pdf)**	
10/20/2017	SUPPL-12	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/202293s012lbl.pdf)**	
03/01/2017	SUPPL-11	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/202293s011lbl.pdf)**	
03/01/2017	SUPPL-11	Labeling-Medication Guide	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/202293s011lbl.pdf)**	

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
08/17/2016	SUPPL-10	Labeling-Medication Guide	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/202293s010lbl.pdf)**	
08/17/2016	SUPPL-10	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/202293s010lbl.pdf)**	
06/14/2016	SUPPL-9	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/202293s009lbl.pdf)**	
12/04/2015	SUPPL-8	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/202293s008lbl.pdf)**	
03/11/2015	SUPPL-2	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/202293s002lbl.pdf)**	
08/08/2014	SUPPL-3	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/202293s003lbl.pdf)**	
01/08/2014	ORIG-1	Approval	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/202293s000lbl.pdf)**	

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Therapeutic Equivalents for NDA 202293

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- Medication Guide (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/202293s030lbl.pdf#page=53)
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Products on NDA 202293

Approval Date(s) and History, Letters, Labels, Reviews for NDA 202293

Labels for NDA 202293

Therapeutic Equivalents for NDA 202293

FARXIGA

TABLET;ORAL; 5MG
TE Code = AB

CSV | Excel | Print

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code	Application No.	Company
FARXIGA	DAPAGLIFLOZIN	5MG	TABLET;ORAL	Prescription	Yes	AB	202293	ASTRAZENECA AB

Showing 1 to 1 of 1 entries

TABLET;ORAL; 10MG
TE Code = AB

CSV | Excel | Print

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code	Application No.	Company
FARXIGA	DAPAGLIFLOZIN	10MG	TABLET;ORAL	Prescription	Yes	AB	202293	ASTRAZENECA AB

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