# Drugs@FDA: FDA-Approved Drugs



**New Drug Application (NDA):** 205649
**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=205649)

- Medication Guide (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/205649s021lbl.pdf#page=59)
- Summary Review (http://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/205649Orig1s000SumR.pdf)

## Products on NDA 205649

CSV | Excel | Print

| Drug Name | Active Ingredients | Strength | Dosage Form/Route | Marketing Status | TE Code | RLD | RS |
|---|---|---|---|---|---|---|---|
| XIGDUO XR | DAPAGLIFLOZIN; METFORMIN HYDROCHLORIDE | 5MG;500MG | TABLET, EXTENDED RELEASE;ORAL | Prescription | None | Yes | No |
| XIGDUO XR | DAPAGLIFLOZIN; METFORMIN HYDROCHLORIDE | 5MG;1GM | TABLET, EXTENDED RELEASE;ORAL | Prescription | None | Yes | No |
| XIGDUO XR | DAPAGLIFLOZIN; METFORMIN HYDROCHLORIDE | 10MG;500MG | TABLET, EXTENDED RELEASE;ORAL | Prescription | None | Yes | No |
| XIGDUO XR | DAPAGLIFLOZIN; METFORMIN HYDROCHLORIDE | 10MG;1GM | TABLET, EXTENDED RELEASE;ORAL | Prescription | None | Yes | Yes |
| XIGDUO XR | DAPAGLIFLOZIN; METFORMIN HYDROCHLORIDE | 2.5MG;1GM | TABLET, EXTENDED RELEASE;ORAL | Prescription | None | Yes | No |

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## Approval Date(s) and History, Letters, Labels, Reviews for NDA 205649

### 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 |
|---|---|---|---|---|---|---|
| 10/29/2014 | ORIG-1 | Approval | Type 4 - New Combination | STANDARD | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/205649s000lbl.pdf)<br>Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/205649Orig1s000ltr.pdf)<br>Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/205649Orig1s000TOC.cfm)<br>Summary Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/205649Orig1s000SumR.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 |
|---|---|---|---|---|
| 09/12/2023 | SUPPL-21 | Labeling-Package Insert | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/205649s021lbl.pdf)<br>Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/202293Orig1s030;205649Orig1s021ltr.pdf) | |
| 10/13/2022 | SUPPL-18 | Labeling-Package Insert | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/205649s018lbl.pdf)<br>Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/202293Orig1s028,205649Orig1s018ltr.pdf) | |
| 04/11/2022 | SUPPL-17 | Efficacy-New Indication | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/205649s017lbl.pdf)<br>Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/205649Orig1s017ltr.pdf) | |
| 02/03/2022 | SUPPL-16 | Efficacy-New Indication | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/205649s016lbl.pdf)<br>Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/205649Orig1s016ltr.pdf) | |
| 02/03/2020 | SUPPL-14 | Labeling-Package Insert, Labeling-Medication Guide | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/205649s014lbl.pdf)<br>Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/202293Orig1s022, 205649Orig1s014ltr.pdf) | |

| Action Date | Submission | Supplement Categories or Approval Type | Letters, Reviews, Labels, Patient Package Insert | Note |
|---|---|---|---|---|
| 01/24/2020 | SUPPL-13 | Labeling-Package Insert | **Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/205649s013lbl.pdf)**<br>**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/202293Orig1s021, 205649Orig1s013, 209091Orig1s005, 210874Orig1s003ltr.pdf)** | |
| 10/18/2019 | SUPPL-11 | Efficacy-New Indication | **Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/205649s011lbl.pdf)**<br>**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/202293Orig1s018, 205649Orig1s011ltr.pdf)** | |
| 08/12/2019 | SUPPL-12 | Manufacturing (CMC)-Control | **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/205649Orig1s012ltr.pdf)** | Label is not available on this site. |
| 02/22/2019 | SUPPL-9 | Efficacy-Labeling Change With Clinical Data | **Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/205649s009lbl.pdf)**<br>**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/202293Orig1s015, 205649Orig1s009ltr.pdf)** | |
| 10/26/2018 | SUPPL-10 | Labeling-Package Insert | **Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/205649s010lbl.pdf)**<br>**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2018/202293Orig1s017,205649Origs010,209091Orig1s003ltr.pdf)** | |
| 07/28/2017 | SUPPL-8 | Manufacturing (CMC)-New Strength | **Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/205649s008lbl.pdf)** | |
| 03/01/2017 | SUPPL-6 | Labeling-Medication Guide, Labeling-Package Insert | **Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/205649s006lbl.pdf )**<br>**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/205649Orig1s006ltr.pdf)** | |
| 01/10/2017 | SUPPL-7 | Manufacturing (CMC) | | Label is not available on this site. |
| 08/17/2016 | SUPPL-5 | Labeling-Package Insert, Labeling-Medication Guide | **Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/205649s005lbl.pdf)**<br>**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/205649Orig1s005ltr.pdf)** | |
| 06/14/2016 | SUPPL-4 | Labeling-Package Insert | **Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/205649s004lbl.pdf)**<br>**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/205649Orig1s004ltr.pdf)** | |
| 01/12/2016 | SUPPL-2 | Manufacturing (CMC) | | Label is not available on this site. |
| 12/04/2015 | SUPPL-3 | Labeling-Package Insert | **Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/205649s003lbl.pdf)**<br>**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/205649Orig1s003ltr.pdf)** | |
| 09/01/2015 | SUPPL-1 | Manufacturing (CMC) | | Label is not available on this site. |

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**Labels for NDA 205649**

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## Products on NDA 205649

## Approval Date(s) and History, Letters, Labels, Reviews for NDA 205649

## Labels for NDA 205649

CSV | Excel | Print

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|---|---|---|---|---|
| 09/12/2023 | SUPPL-21 | Labeling-Package Insert | **Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/205649s021lbl.pdf)** | |
| 10/13/2022 | SUPPL-18 | Labeling-Package Insert | **Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/205649s018lbl.pdf)** | |
| 04/11/2022 | SUPPL-17 | Efficacy-New Indication | **Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/205649s017lbl.pdf)** | |
| 02/03/2022 | SUPPL-16 | Efficacy-New Indication | **Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/205649s016lbl.pdf)** | |
| 02/03/2020 | SUPPL-14 | Labeling-Package Insert | **Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/205649s014lbl.pdf)** | |
| 02/03/2020 | SUPPL-14 | Labeling-Medication Guide | **Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/205649s014lbl.pdf)** | |
| 01/24/2020 | SUPPL-13 | Labeling-Package Insert | **Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/205649s013lbl.pdf)** | |
| 10/18/2019 | SUPPL-11 | Efficacy-New Indication | **Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/205649s011lbl.pdf)** | |
| 02/22/2019 | SUPPL-9 | Efficacy-Labeling Change With Clinical Data | **Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/205649s009lbl.pdf)** | |
| 10/26/2018 | SUPPL-10 | Labeling-Package Insert | **Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/205649s010lbl.pdf)** | |
| 07/28/2017 | SUPPL-8 | Manufacturing (CMC)-New Strength | **Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/205649s008lbl.pdf)** | |
| 03/01/2017 | SUPPL-6 | Labeling-Medication Guide | **Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/205649s006lbl.pdf )** | |
| 03/01/2017 | SUPPL-6 | Labeling-Package Insert | **Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/205649s006lbl.pdf )** | |
| 08/17/2016 | SUPPL-5 | Labeling-Package Insert | **Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/205649s005lbl.pdf)** | |
| 08/17/2016 | SUPPL-5 | Labeling-Medication Guide | **Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/205649s005lbl.pdf)** | |

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| 12/04/2015 | SUPPL-3 | Labeling-Package Insert | **Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/205649s003lbl.pdf)** | |
| 10/29/2014 | ORIG-1 | Approval | **Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/205649s000lbl.pdf)** | |

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