Drugs@FDA: FDA-Approved Drugs

New Drug Application (NDA): 209803
Company: MSD SUB MERCK

EMAIL (MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=209803)

- Medication Guide (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209803s007lbl.pdf#page=25)

Products on NDA 209803

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
STEGLATRO	ERTUGLIFLOZIN	5MG	TABLET;ORAL	Prescription	AB	Yes	No
STEGLATRO	ERTUGLIFLOZIN	15MG	TABLET;ORAL	Prescription	AB	Yes	Yes

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Approval Date(s) and History, Letters, Labels, Reviews for NDA 209803

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
12/19/2017	ORIG-1	Approval	Type 1 - New Molecular Entity	STANDARD	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209803s000lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/209803Orig1s000ltr.pdf) Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209803,209805,209806Orig1s000TOC.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-7	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209803s007lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/209803Orig1s007;209805Orig1s016;209806Orig1s010ltr.pdf)	
10/13/2022	SUPPL-6	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/209803s006lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/209803Orig1s006,209805Orig1s012,209806Orig1s009ltr.pdf)	
09/17/2021	SUPPL-4	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/209803s004lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2021/209803Orig1s004; 209805Orig1s008; 209806Orig1s006ltr.pdf)	
01/24/2020	SUPPL-2	Labeling-Medication Guide, Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/209803s002lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/209803Orig1s002,209805Orig1s006,209806Orig1s002ltr.pdf)	
10/26/2018	SUPPL-1	Labeling-Medication Guide, Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/209803s001lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2018/209803Orig1s001ltr.pdf)	

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Labels for NDA 209803

Therapeutic Equivalents for NDA 209803

Drugs@FDA: FDA-Approved Drugs

New Drug Application (NDA): 209803
Company: MSD SUB MERCK

EMAIL (MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=209803)

- Medication Guide (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209803s007lbl.pdf#page=25)

Products on NDA 209803

Approval Date(s) and History, Letters, Labels, Reviews for NDA 209803

Labels for NDA 209803

CSV | Excel | Print

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
09/12/2023	SUPPL-7	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209803s007lbl.pdf)**	
10/13/2022	SUPPL-6	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/209803s006lbl.pdf)**	
09/17/2021	SUPPL-4	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/209803s004lbl.pdf)**	
01/24/2020	SUPPL-2	Labeling-Medication Guide	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/209803s002lbl.pdf)**	
01/24/2020	SUPPL-2	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/209803s002lbl.pdf)**	
10/26/2018	SUPPL-1	Labeling-Medication Guide	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/209803s001lbl.pdf)**	
10/26/2018	SUPPL-1	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/209803s001lbl.pdf)**	
12/19/2017	ORIG-1	Approval	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209803s000lbl.pdf)**	

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Therapeutic Equivalents for NDA 209803

Drugs@FDA: FDA-Approved Drugs

New Drug Application (NDA): 209803
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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=209803)

- Medication Guide (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209803s007lbl.pdf#page=25)

Products on NDA 209803

Approval Date(s) and History, Letters, Labels, Reviews for NDA 209803

Labels for NDA 209803

Therapeutic Equivalents for NDA 209803

STEGLATRO

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
STEGLATRO	ERTUGLIFLOZIN	5MG	TABLET;ORAL	Prescription	Yes	AB	209803	MSD SUB MERCK

Showing 1 to 1 of 1 entries

TABLET;ORAL; 15MG
TE Code = AB

CSV | Excel | Print

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code	Application No.	Company
STEGLATRO	ERTUGLIFLOZIN	15MG	TABLET;ORAL	Prescription	Yes	AB	209803	MSD SUB MERCK

Showing 1 to 1 of 1 entries