Drugs@FDA: FDA-Approved Drugs

New Drug Application (NDA): 022271
Company: TAKEDA PHARMS USA

EMAIL (MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=022271)

- Medication Guide (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/022271s015lbl.pdf#page=28)
- Summary Review (http://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/022271Orig1s000SumR.pdf)

Products on NDA 022271

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
NESINA	ALOGLIPTIN BENZOATE	EQ 6.25MG BASE	TABLET;ORAL	Prescription	None	Yes	No
NESINA	ALOGLIPTIN BENZOATE	EQ 12.5MG BASE	TABLET;ORAL	Prescription	None	Yes	No
NESINA	ALOGLIPTIN BENZOATE	EQ 25MG BASE	TABLET;ORAL	Prescription	None	Yes	Yes

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Approval Date(s) and History, Letters, Labels, Reviews for NDA 022271

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
01/25/2013	ORIG-1	Approval	Type 1 - New Molecular Entity	STANDARD	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/022271s000lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2013/022271Orig1s000ltr.pdf) Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/022271Orig1s000TOC.cfm) Summary Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/022271Orig1s000SumR.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
07/27/2023	SUPPL-15	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/022271s015lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/022271Orig1s015;203414Orig1s016ltr.pdf)	
03/11/2022	SUPPL-13	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/022271s013lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/022271Orig1s013; 022426Orig1s014; 203414Orig1s013ltr.pdf)	
07/01/2019	SUPPL-12	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/022271s012lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/022271Orig1s012, 022426Orig1s012, 203414Orig1s012ltr.pdf)	
12/12/2016	SUPPL-11	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/022271s011lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/022271Orig1s011ltr.pdf)	
05/27/2016	SUPPL-9	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/022271s009lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/022271Orig1s009ltr.pdf)	

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
04/19/2016	SUPPL-8	Manufacturing (CMC)		Label is not available on this site.
04/05/2016	SUPPL-5	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/022271s005lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/022271Orig1s005,022426Orig1s003,203414Orig1s003ltr.pdf)**	
08/28/2015	SUPPL-7	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/022271s007lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/022271Orig1s007,022426Orig1s005,203414Orig1s005ltr.pdf)**	
07/20/2015	SUPPL-6	Manufacturing (CMC)		Label is not available on this site.
08/15/2013	SUPPL-3	Manufacturing (CMC)		Label is not available on this site.
06/26/2013	SUPPL-2	Manufacturing (CMC)		Label is not available on this site.
05/30/2013	SUPPL-1	Manufacturing (CMC)		Label is not available on this site.

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Labels for NDA 022271

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Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
07/27/2023	SUPPL-15	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/022271s015lbl.pdf)**	
03/11/2022	SUPPL-13	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/022271s013lbl.pdf)**	
07/01/2019	SUPPL-12	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/022271s012lbl.pdf)**	
12/12/2016	SUPPL-11	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/022271s011lbl.pdf)**	
05/27/2016	SUPPL-9	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/022271s009lbl.pdf)**	
04/05/2016	SUPPL-5	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/022271s005lbl.pdf)**	
08/28/2015	SUPPL-7	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/022271s007lbl.pdf)**	
01/25/2013	ORIG-1	Approval	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/022271s000lbl.pdf)**	

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