Drugs@FDA: FDA-Approved Drugs

New Drug Application (NDA): 022350
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=022350)

- Medication Guide (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/022350s023lbl.pdf#page=31)
- Summary Review (http://www.accessdata.fda.gov/drugsatfda_docs/nda/2009/022350s000_SumR.pdf)

Products on NDA 022350

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
ONGLYZA	SAXAGLIPTIN HYDROCHLORIDE	EQ 2.5MG BASE	TABLET;ORAL	Discontinued	None	Yes	No
ONGLYZA	SAXAGLIPTIN HYDROCHLORIDE	EQ 5MG BASE	TABLET;ORAL	Discontinued	None	Yes	No

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Approval Date(s) and History, Letters, Labels, Reviews for NDA 022350

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
07/31/2009	ORIG-1	Approval	Type 1 - New Molecular Entity	STANDARD	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/022350lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2009/022350s000ltr.pdf) Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2009/022350s000TOC.cfm) Summary Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2009/022350s000_SumR.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
07/01/2019	SUPPL-23	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/022350s023lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/022350Orig1s023, 200678Orig1s024, 209091Orig1s004, 210874Orig1s001ltr.pdf)	
02/27/2017	SUPPL-18	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/022350s018lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/022350Orig1s018,200678Orig1s018ltr.pdf)	
01/18/2017	SUPPL-19	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/022350s019lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/022350Orig1s019ltr.pdf)	
04/05/2016	SUPPL-14	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/022350s014lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/022350Orig1s014,200678Orig1s013ltr.pdf)	
11/25/2015	SUPPL-17	Manufacturing (CMC)		Label is not available on this site.

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
08/28/2015	SUPPL-16	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/022350s016lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/022350Orig1s016,200678Orig1s016ltr.pdf)**	
01/23/2014	SUPPL-13	Manufacturing (CMC)		Label is not available on this site.
05/24/2013	SUPPL-11	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/022350s011lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2013/022350Orig1s011ltr.pdf)**	
03/13/2012	SUPPL-9	Labeling-Package Insert	**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2012/022350s009ltr.pdf)**	Label is not available on this site.
12/16/2011	SUPPL-4	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022350s004lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/022350s004ltr.pdf)**	
11/15/2011	SUPPL-7	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022350s007lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/022350s007ltr.pdf)**	
02/18/2011	SUPPL-2	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022350s001s002lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/022350s001,s002ltr.pdf)**	
02/18/2011	SUPPL-1	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022350s001s002lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/022350s001,s002ltr.pdf)**	

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Labels for NDA 022350

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Products on NDA 022350

Approval Date(s) and History, Letters, Labels, Reviews for NDA 022350

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07/01/2019	SUPPL-23	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/022350s023lbl.pdf)**	
02/27/2017	SUPPL-18	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/022350s018lbl.pdf)**	
01/18/2017	SUPPL-19	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/022350s019lbl.pdf)**	
04/05/2016	SUPPL-14	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/022350s014lbl.pdf)**	
08/28/2015	SUPPL-16	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/022350s016lbl.pdf)**	
05/24/2013	SUPPL-11	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/022350s011lbl.pdf)**	
12/16/2011	SUPPL-4	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022350s004lbl.pdf)**	
11/15/2011	SUPPL-7	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022350s007lbl.pdf)**	
02/18/2011	SUPPL-2	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022350s001s002lbl.pdf)**	
02/18/2011	SUPPL-1	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022350s001s002lbl.pdf)**	
07/31/2009	ORIG-1	Approval	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/022350lbl.pdf)**	

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