

Drugs@FDA: FDA-Approved Drugs

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New Drug Application (NDA): 021073
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=021073)

- [Medication Guide \(https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/021073s049lbl.pdf#page=35\)](https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/021073s049lbl.pdf#page=35)

Products on NDA 021073

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
ACTOS	PIOGLITAZONE HYDROCHLORIDE	EQ 15MG BASE	TABLET;ORAL	Prescription	AB	Yes	No
ACTOS	PIOGLITAZONE HYDROCHLORIDE	EQ 30MG BASE	TABLET;ORAL	Prescription	AB	Yes	No
ACTOS	PIOGLITAZONE HYDROCHLORIDE	EQ 45MG BASE	TABLET;ORAL	Prescription	AB	Yes	Yes

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Approval Date(s) and History, Letters, Labels, Reviews for NDA 021073

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
07/15/1999	ORIG-1	Approval	Type 1 - New Molecular Entity	PRIORITY	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/1999/21073lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/1999/21073ltr.pdf) Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/99/021073A_Actos.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
12/21/2017	SUPPL-49	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/021073s049lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2017/021073orig1s049ltr.pdf)	
12/12/2016	SUPPL-48	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/021073s048lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2016/021073orig1s048ltr.pdf)	
11/12/2013	SUPPL-46	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/021073s046lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2013/021073orig1s046ltr.pdf)	
06/27/2013	SUPPL-47	Manufacturing (CMC)		Label is not available on this site.

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
05/17/2012	SUPPL-45	REMS-Assessment	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2012/021073s045_021842s016_022024s009_021925s012ltr.pdf)	Label is not available on this site.
08/04/2011	SUPPL-44	Labeling-Package Insert, Labeling-Medication Guide	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021073s043s044lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2011/021073Orig1s043s044-021842Orig1s014s015-022024Orig1s008s007-021925Orig1s010s011ltr.pdf)	
08/04/2011	SUPPL-43	REMS-Modified	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021073s043s044lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2011/021073Orig1s043s044-021842Orig1s014s015-022024Orig1s008s007-021925Orig1s010s011ltr.pdf)	
02/03/2011	SUPPL-35	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021073s035lbl.pdf)	
07/29/2010	SUPPL-40	Labeling-Container/ Carton Labels	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2010/021073s040ltr.pdf)	Label is not available on this site.
09/09/2009	SUPPL-37	Labeling, REMS-Proposal	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021073s037lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2009/021073s037ltr.pdf)	
12/11/2008	SUPPL-34	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021073s034lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2008/021073s034ltr.pdf)	
05/07/2008	SUPPL-33	Labeling	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2008/021073s033ltr.pdf) Patient Package Insert (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021073s033PI.pdf)	Label is not available on this site.
09/06/2007	SUPPL-30	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/021073s030lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2007/021073s030_ltr.pdf)	
08/14/2007	SUPPL-31	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/021073s031lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2007/021073s031LTR.pdf)	
02/25/2007	SUPPL-26	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/021073s026lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2007/021073s026ltr.pdf)	
11/04/2006	SUPPL-28	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/021073s028_021842s002lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2006/021073s028_021842S002ltr.pdf)	
09/28/2006	SUPPL-29	Labeling	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2006/021073s029_021842s003LTR.pdf)	Label is not available on this site.
08/30/2006	SUPPL-27	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/021073s027lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2006/021073s027ltr.pdf)	
08/03/2004	SUPPL-23	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2004/21073s023lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2004/21073s023ltr.pdf) Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2004/021073_s023_ACTOS TABS.pdf)	
07/20/2004	SUPPL-24	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2004/21073s024lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2004/21073s024ltr.pdf) Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2004/021073_s024_ACTOS TABS.pdf)	
11/26/2003	SUPPL-20	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2003/21073se8-020_actos_lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2003/21073se8-020ltr.pdf) Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2003/021073_S020_ACTOS TABLETS_AP.pdf)	
06/11/2003	SUPPL-21	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2003/21073slr071_actos_lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2003/21073slr071ltr.pdf)	
01/17/2003	SUPPL-17	Efficacy-Labeling Change With Clinical Data	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2003/21073se8-017ltr.pdf)	Label is not available on this site.

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
12/03/2002	SUPPL-18	Manufacturing (CMC)-Packaging	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2002/21073scp018ltr.pdf)	Label is not available on this site.
10/01/2002	SUPPL-13	Manufacturing (CMC)-Control	Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2002/021073_S013_ACTOS_TABLETS.pdf)	Label is not available on this site.
07/12/2002	SUPPL-10	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2002/21073s10lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2002/21073se8010ltr.pdf) Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2002/021073_S010_Actos Tablets_APPROVAL PACKAGE.pdf)	
02/28/2002	SUPPL-15	Manufacturing (CMC)-Control	Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2002/021073_S015_ACTOS_TABLETS.pdf)	Label is not available on this site.
01/07/2002	SUPPL-16	Labeling	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2002/21073s16ltr.pdf) Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2002/021073_S016_ACTOS.pdf)	Label is not available on this site.
08/03/2001	SUPPL-14	Manufacturing (CMC)	Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2001/021073_S014_ACTOS.pdf)	Label is not available on this site.
07/06/2001	SUPPL-9	Manufacturing (CMC)		Label is not available on this site.
07/06/2001	SUPPL-8	Manufacturing (CMC)	Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2001/021073_S008_ACTOS TABLETS.pdf)	Label is not available on this site.
07/02/2001	SUPPL-11	Labeling		Label is not available on this site.
05/22/2001	SUPPL-12	Manufacturing (CMC)	Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2001/021073_S012_ACTOS TABLETS.pdf)	Label is not available on this site.
04/25/2001	SUPPL-7	Manufacturing (CMC)	Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2001/021073_S007_ACTOS.pdf)	Label is not available on this site.
11/03/2000	SUPPL-6	Manufacturing (CMC)	Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/021073_S006_ACTOS.pdf)	Label is not available on this site.
10/25/2000	SUPPL-4	Manufacturing (CMC)-Control	Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/021073_S004_ACTOS.pdf)	Label is not available on this site.

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
07/26/2000	SUPPL-5	Manufacturing (CMC)	Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/021073_S005_ACTOS.pdf)	Label is not available on this site.
04/11/2000	SUPPL-3	Manufacturing (CMC)	Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/021073_S003_ACTOS.pdf)	Label is not available on this site.
02/25/2000	SUPPL-2	Manufacturing (CMC)-Control	Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/021073_S002_ACTOS.pdf)	Label is not available on this site.
02/25/2000	SUPPL-1	Manufacturing (CMC)-Packaging	Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/021073_S001_ACTOS.pdf)	Label is not available on this site.

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[Labels for NDA 021073](#) ▼

[Therapeutic Equivalents for NDA 021073](#) ▼

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New Drug Application (NDA): 021073

Company: TAKEDA PHARMS USA

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- [Medication Guide \(https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/021073s049lbl.pdf#page=35\)](https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/021073s049lbl.pdf#page=35)

Products on NDA 021073

Approval Date(s) and History, Letters, Labels, Reviews for NDA 021073

Labels for NDA 021073

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Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
12/21/2017	SUPPL-49	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/021073s049lbl.pdf)	
12/12/2016	SUPPL-48	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/021073s048lbl.pdf)	
11/12/2013	SUPPL-46	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/021073s046lbl.pdf)	
08/04/2011	SUPPL-44	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021073s043s044lbl.pdf)	
08/04/2011	SUPPL-44	Labeling-Medication Guide	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021073s043s044lbl.pdf)	
08/04/2011	SUPPL-43	REMS-Modified	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021073s043s044lbl.pdf)	
02/03/2011	SUPPL-35	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021073s035lbl.pdf)	
09/09/2009	SUPPL-37	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021073s037lbl.pdf)	
09/09/2009	SUPPL-37	REMS-Proposal	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021073s037lbl.pdf)	
12/11/2008	SUPPL-34	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021073s034lbl.pdf)	
09/06/2007	SUPPL-30	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/021073s030lbl.pdf)	
08/14/2007	SUPPL-31	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/021073s031lbl.pdf)	
02/25/2007	SUPPL-26	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/021073s026lbl.pdf)	
11/04/2006	SUPPL-28	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/021073s028,021842s002lbl.pdf)	
08/30/2006	SUPPL-27	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/021073s027lbl.pdf)	
08/03/2004	SUPPL-23	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2004/21073s023lbl.pdf)	
07/20/2004	SUPPL-24	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2004/21073s024lbl.pdf)	
11/26/2003	SUPPL-20	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2003/21073se8-020_actos_lbl.pdf)	
06/11/2003	SUPPL-21	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2003/21073slr071_actos_lbl.pdf)	

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