

Drugs@FDA: FDA Approved Drug Products

f [SHARE \(HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=BASICSEARCH.PROCESS\)](https://www.facebook.com/sharer/sharer.php?u=https://www.accessdata.fda.gov/scripts/cder/da/index.cfm?event=basicsearch.process)

t [TWEET \(HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=BASICSEARCH.PROCESS\)](https://twitter.com/intent/tweet?text=drugs@fda: fda approved drug products&url=https://www.accessdata.fda.gov/scripts/cder/da/index.cfm?event=basicsearch.process)



e [EMAIL \(MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=BASICSEARCH.PROCESS\)](mailto:?subject=drugs@fda: fda approved drug products&body=https://www.accessdata.fda.gov/scripts/cder/da/index.cfm?event=basicsearch.process)

[Home \(index.cfm\)](#) | [Previous Page](#)

New Drug Application (NDA): 022332

Company: ELI LILLY CO

e [EMAIL \(MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=022332\)](mailto:?subject=drugs@fda: fda approved drug products&body=http://www.accessdata.fda.gov/scripts/cder/da/index.cfm?event=overview.process%26varapplno=022332)

Products on NDA 022332

CSVExcelPrint

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code
ADCIRCA	TADALAFIL	20MG	TABLET;ORAL	Prescription	Yes	None

Showing 1 to 1 of 1 entries

Approval Date(s) and History, Letters, Labels, Reviews for NDA 022332

Original Approvals or Tentative Approvals

CSVExcelPrint

Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels
05/22/2009	ORIG-1	Approval	Type 6 - New Indication (no longer used)	STANDARD	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/05/22/09122332s01.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/letter/2009/05/22/09122332s01.pdf) Review (https://www.accessdata.fda.gov/drugsatfda_docs/review/2009/05/22/09122332s01.pdf)

Showing 1 to 1 of 1 entries

Supplements**CSVExcelPrint**

Action Date	Submission	Submission Classification	Letters, Reviews, Labels, Patient Package Insert
05/05/2017	SUPPL-9	Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/022332s01.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2017/022332s01.pdf)
04/02/2015	SUPPL-7	Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/022332s01.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2015/022332s01.pdf)
04/29/2014	SUPPL-6	Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022332s01.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2014/022332s01.pdf)
11/20/2013	SUPPL-5	Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/022332s01.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2013/022332s01.pdf)
02/08/2011	SUPPL-3	Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022332s01.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2011/022332s01.pdf)

Showing 1 to 5 of 5 entries

Labels for NDA 022332

