

Mkt.Status	Active Ingredient	Proprietary Name	Appl No	Product Number	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder	Approval Date
DISCN	TERBINAFINE HYDROCHLORIDE	LAMISIL	N020192	001	CREAM	TOPICAL	1%				NOVARTIS PHARMACEUTICALS CORP	Dec 30, 1992
OTC	TERBINAFINE HYDROCHLORIDE	LAMISIL	N020980	001	CREAM	TOPICAL	1%		RLD	RS	GLAXOSMITHKLINE CONSUMER HEALTHCARE HOLDINGS (US) LLC	Mar 9, 1999
OTC	TERBINAFINE HYDROCHLORIDE	TERBINAFINE HYDROCHLORIDE	A077511	001	CREAM	TOPICAL	1%				TARO PHARMACEUTICALS USA INC	Jul 2, 2007
DISCN	TERBINAFINE	LAMISIL	N020846	001	GEL	TOPICAL	1%				GLAXOSMITHKLINE CONSUMER HEALTHCARE	Apr 29, 1998
OTC	TERBINAFINE	LAMISIL AT	N021958	001	GEL	TOPICAL	1%		RLD	RS	NOVARTIS CONSUMER HEALTH INC	Jul 24, 2006
DISCN	TERBINAFINE HYDROCHLORIDE	LAMISIL	N022071	001	GRANULE	ORAL	EQ 125MG BASE/PACKET		RLD	RS	NOVARTIS PHARMACEUTICALS CORP	Sep 28, 2007
DISCN	TERBINAFINE HYDROCHLORIDE	LAMISIL	N022071	002	GRANULE	ORAL	EQ 187.5MG BASE/PACKET		RLD	RS	NOVARTIS PHARMACEUTICALS CORP	Sep 28, 2007
DISCN	TERBINAFINE HYDROCHLORIDE	LAMISIL	N020749	001	SOLUTION	TOPICAL	1%				GLAXOSMITHKLINE CONSUMER HEALTHCARE	Oct 17, 1997
OTC	TERBINAFINE HYDROCHLORIDE	LAMISIL AT	N021124	001	SOLUTION	TOPICAL	1%		RLD	RS	NOVARTIS CONSUMER HEALTH INC	Mar 17, 2000
OTC	TERBINAFINE HYDROCHLORIDE	LAMISIL AT	N021124	002	SPRAY	TOPICAL	1%		RLD	RS	NOVARTIS CONSUMER HEALTH INC	Mar 17, 2000
XX	TERBINAFINE HYDROCHLORIDE	LAMISIL	N020539	001	TABLET	ORAL	EQ 250MG BASE	AB	RLD	RS	NOVARTIS PHARMACEUTICALS CORP	May 10, 1996
XX	TERBINAFINE HYDROCHLORIDE	TERBINAFINE HYDROCHLORIDE	A078199	001	TABLET	ORAL	EQ 250MG BASE	AB			APOTEX CORP	Jul 2, 2007
XX	TERBINAFINE HYDROCHLORIDE	TERBINAFINE HYDROCHLORIDE	A078297	001	TABLET	ORAL	EQ 250MG BASE	AB			AUROBINDO PHARMA LTD	Jul 2, 2007
XX	TERBINAFINE HYDROCHLORIDE	TERBINAFINE HYDROCHLORIDE	A077137	001	TABLET	ORAL	EQ 250MG BASE	AB			CIPLA LTD	Jul 2, 2007
XX	TERBINAFINE HYDROCHLORIDE	TERBINAFINE HYDROCHLORIDE	A076390	001	TABLET	ORAL	EQ 250MG BASE	AB			DR REDDYS LABORATORIES INC	Jul 2, 2007
XX	TERBINAFINE HYDROCHLORIDE	TERBINAFINE HYDROCHLORIDE	A078157	001	TABLET	ORAL	EQ 250MG BASE	AB			GLENMARK GENERICS LTD	Jul 2, 2007
XX	TERBINAFINE HYDROCHLORIDE	TERBINAFINE HYDROCHLORIDE	A077919	001	TABLET	ORAL	EQ 250MG BASE	AB			HARRIS PHARMACEUTICAL INC	Jul 2, 2007
XX	TERBINAFINE HYDROCHLORIDE	TERBINAFINE HYDROCHLORIDE	A077533	001	TABLET	ORAL	EQ 250MG BASE	AB			INVAGEN PHARMACEUTICALS INC	Jul 2, 2007
XX	TERBINAFINE HYDROCHLORIDE	TERBINAFINE HYDROCHLORIDE	A078163	001	TABLET	ORAL	EQ 250MG BASE	AB			ORCHID HEALTHCARE	Jul 2, 2007
XX	TERBINAFINE HYDROCHLORIDE	TERBINAFINE HYDROCHLORIDE	A076377	001	TABLET	ORAL	EQ 250MG BASE	AB			TEVA PHARMACEUTICALS USA INC	Jul 2, 2007
DISCN	TERBINAFINE HYDROCHLORIDE	TERBINAFINE HYDROCHLORIDE	A077065	001	TABLET	ORAL	EQ 250MG BASE				GEDEON RICHTER USA INC	Jul 2, 2007
DISCN	TERBINAFINE HYDROCHLORIDE	TERBINAFINE HYDROCHLORIDE	A077136	001	TABLET	ORAL	EQ 250MG BASE				MYLAN PHARMACEUTICALS INC	Jul 2, 2007
DISCN	TERBINAFINE HYDROCHLORIDE	TERBINAFINE HYDROCHLORIDE	A077195	001	TABLET	ORAL	EQ 250MG BASE				MYLAN PHARMACEUTICALS INC	Jul 2, 2007
DISCN	TERBINAFINE HYDROCHLORIDE	TERBINAFINE HYDROCHLORIDE	A077223	001	TABLET	ORAL	EQ 250MG BASE				ROXANE LABORATORIES INC	Jul 2, 2007
DISCN	TERBINAFINE HYDROCHLORIDE	TERBINAFINE HYDROCHLORIDE	A078229	001	TABLET	ORAL	EQ 250MG BASE				WOCKHARDT LTD	Jul 2, 2007
XX	TERBINAFINE HYDROCHLORIDE	TERBINAFINE HYDROCHLORIDE	A077714	001	TABLET	ORAL	EQ 250MG BASE	AB			BRECKENRIDGE PHARMACEUTICAL INC	Jun 4, 2010

**Source:** "Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations: Search results for Terbinafine." *U.S. Food & Drug*. Accessed on November 1, 2017.  
[https://www.accessdata.fda.gov/scripts/cder/ob/search\\_product.cfm](https://www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm).