

FINASTERIDE - finasteride tablet, film coated
Zydus Lifesciences Limited

FINASTERIDE TABLETS

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1152-0 in bottle of 1000 tablets

Finasteride Tablets USP, 5 mg

R_x only

1000 tablets

ZyGenerics
NDC 70771-1152-0
FINASTERIDE
Tablets USP
5 mg

Each tablet contains:
Finasteride, USP 5 mg

Usual Adult Dosage: 5 mg once a day.
See package insert for complete prescribing information.

Store at 20° to 25°C with excursions permitted between 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature]. Protect from light. Keep container tightly closed.

Dispense in a tight, light-resistant container.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

WARNING: Finasteride tablets should not be used by women or children. Women who are or may potentially be pregnant must not use finasteride tablets. They should also not handle crushed or broken tablets of finasteride. (See package insert).

PHARMACIST:
Dispense with Patient Information Leaflet

Rx only
1000 Tablets

Lot:
Exp:
Rev.: 11/17

FINASTERIDE

finasteride tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1152
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FINASTERIDE (UNII: 57GNO57U7G) (FINASTERIDE - UNII:57GNO57U7G)	FINASTERIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
DOCUSATE SODIUM (UNII: F05Q2T2JA0)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYDROXYPROPYL CELLULOSE (160000 WAMW) (UNII: RFW2ET671P)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SHELLAC (UNII: 46N107B71O)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	

Product Characteristics

Color	BLUE (blue)	Score	no score
Shape	ROUND (ROUND)	Size	6mm
Flavor		Imprint Code	ZE;56
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1152-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2017	
2	NDC:70771-1152-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2017	
3	NDC:70771-1152-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2017	
4	NDC:70771-1152-4	10 in 1 CARTON	12/05/2017	
4		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078900	12/05/2017	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zyduş Lifesciences Limited		918596198	ANALYSIS(70771-1152) , MANUFACTURE(70771-1152)

Revised: 10/2022

Zyduş Lifesciences Limited