

TERIFLUNOMIDE- teriflunomide tablet, film coated
Zydus Lifesciences Limited

Teriflunomide Tablets

SPL MEDGUIDE

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1010-3

Teriflunomide Tablets, 7 mg

30 Tablets

Rx only

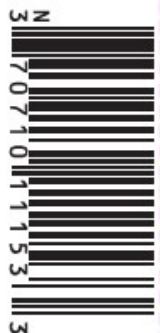


NDC 70771-1011-3

Teriflunomide Tablets, 14 mg

30 Tablets

Rx only



GUJ/DRUGS/G/25/1932
Rev.: 07/24

Teriflunomide Tablets

14 mg

Dispense the Medication Guide
provided separately to each patient.



30 Tablets
Rx only

Each tablet contains:
Teriflunomide 14 mg
Usual dosage: One tablet orally once daily
(See package insert).
Teriflunomide Tablets can be taken with
or without food.
This package is child-resistant.
Store at 20°C to 25°C (68°F to 77°F);
excursions permitted between 15°C
and 30°C (59°F and 86°F).
WARNING: Keep out of the reach of children.
Medication Guide available at
www.zydususa.com/medguides
or call 1-877-993-8779.
Manufactured by: Zydus Lifesciences Ltd.
Ahmedabad, India

TERIFLUNOMIDE

teriflunomide tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1010
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TERIFLUNOMIDE (UNII: 1C058IKG3B) (TERIFLUNOMIDE - UNII:1C058IKG3B)	TERIFLUNOMIDE	7 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (WHITE TO OFF WHITE)	Score	no score
Shape	ROUND (ROUND)	Size	6mm
Flavor		Imprint Code	1114
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1010-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/14/2023	
2	NDC:70771-1010-8	2 in 1 CARTON	02/14/2023	
2	NDC:70771-1010-7	1 in 1 CARTON		
2		14 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	ANDA209668	02/14/2023	

TERIFLUNOMIDE

teriflunomide tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1011
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TERIFLUNOMIDE (UNII: 1C058IKG3B) (TERIFLUNOMIDE - UNII:1C058IKG3B)	TERIFLUNOMIDE	14 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BLUE (BLUE TO LIGHT BLUE)	Score	no score
Shape	ROUND (ROUND)	Size	8mm
Flavor		Imprint Code	1115
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1011-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/14/2023	
2	NDC:70771-1011-8	2 in 1 CARTON	02/14/2023	
2	NDC:70771-1011-7	1 in 1 CARTON		
2		14 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	ANDA209668	02/14/2023	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1010, 70771-1011) , MANUFACTURE(70771-1010, 70771-1011)

Revised: 8/2024

Zydus Lifesciences Limited