# TENOFOVIR DISOPROXIL FUMARATE- tenofovir disoproxil fumarate tablet, film coated AIZANT DRUG RESEARCH SOLUTIONS PVT LTD

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

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These highlights do not include all the information needed to use Tenofovir disoproxil Fumarate Tablets safely and effectively. See full prescribing information for tenofovir disoproxil fumarate tablets.

Tenofovir disoproxil fumarate tablets, for oral use Initial U.S. Approval: 2001

#### 16 HOW SUPPLIED/STORAGE AND HANDLING

Tenofovir disoproxiltablets, 150 mg, are triangle-shaped, white, film-coated tablets containing 150 mg of tenofovir disoproxilfumarate, which is equivalent to 123 mg of tenofovir disoproxil, are debossed with "100" onone side and "A" on the other side. Each bottle contains 30 tablets, a desiccant (1g silica gel canisteror sachet), and closed with a child-resistant closure. (NDC 69025-100-01)

Tenofovir disoproxiltablets, 200 mg, are round-shaped, white, film-coated tablets containing 200 mg of tenofovirdisoproxilfumarate, which is equivalent to 163 mg of tenofovir disoproxil, are debossed with "101" onone side and "A" on the other side. Each bottle contains 30 tablets, a desiccant (1g silica gelcanister or sachet), and closed with a child-resistant closure. (NDC 69025-101-01)

Tenofovir disoproxiltablets, 250 mg, are capsule-shaped, white, film-coated tablets containing 250 mg of tenofovirdisoproxilfumarate, which is equivalent to 204 mg of tenofovir disoproxil, are debossed with "102" onone side and "A" on the other side. Each bottle contains 30 tablets, a desiccant (1g silica gel canisteror sachet), and closed with a child-resistant closure. (NDC 69025-102-01)

Tenofovir disoproxiltablets, 300 mg, are almond-shaped, light blue, film-coated tablets containing 300 mg oftenofovir disoproxilfumarate, which is equivalent to 245 mg of tenofovir disoproxil, are debossedwith "103" on one side and "A" on the other side. Each bottle contains 30tablets, a desiccant (1g silica gel canister or sachet), and closed with a child-resistant closure. (NDC 69025-103-01)

### PRINCIPAL DISPLAY PANEL

### **Tenofovir Disoproxil Fumarate Tablets**

NDC 69025-100-01 150 mg - 30 Tablets Rx only



### **Tenofovir Disoproxil Fumarate Tablets**

NDC 69025-101-01 200 mg - 30 Tablets Rx only



### **Tenofovir Disoproxil Fumarate Tablets**

NDC 69025-102-01 250 mg - 30 Tablets Rx only Tenofovir Disoproxil
Fumarate Tablets
Each tablet contains
250 mg of tenofovir
disoproxil fumarate, which
is equivalent to 204 mg
of tenofovir disoproxil.
Store at 25 °C (77 °F) (see insert).
Keep container tightly
closed. Dispense only
in original container.
Usual Dosage:
See Prescribing Information.
Manufactured by:
Aizant Drug Research Solutions

Survey No. 172 / 173, Apparel Park Road, Dulapally Village, Qutbullaphur Mandal

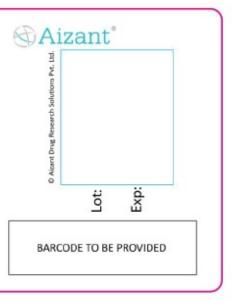
Hyderabad 500014 Andhra Pradesh, India

Made in India Mfg. Lic. No.: Tenofovir Disoproxil Fumarate Tablets

250 mg

30 tablets R only

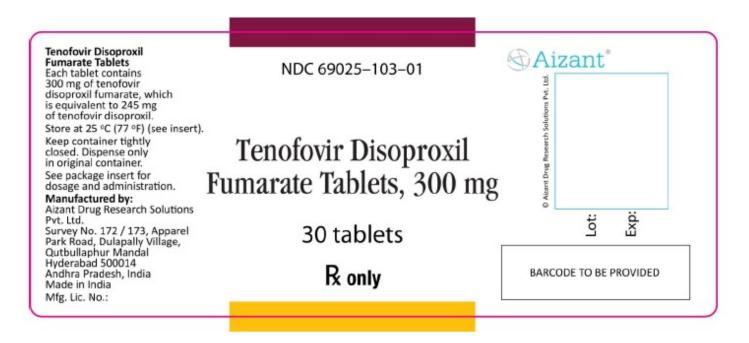
NDC 69025-102-01



### **Tenofovir Disoproxil Fumarate Tablets**

NDC 69025-103-01 300 mg - 30 Tablets Rx only

Pvt. Ltd.



# TENOFOVIR DISOPROXIL FUMARATE tenofovir disoproxil fumarate tablet, film coated Product Information Product Type HUMAN PRESCRIPTION DRUG Item Code (Source) NDC:69025-100 Route of Administration ORAL

l	Active Ingredient/Active Moiety					
l	Ingredient Name	Basis of Strength Stre				
	tenofovir disoproxil fumarate (UNII: OTT9J7900I) (tenofovir anhydrous - UNII:W4HFE001U5)	tenofovir disoproxil fumarate	150 mg			

Product Characteristics					
Color	white	Score	no score		
Shape	TRIANGLE	Size	10 mm		
Flavor		Imprint Code	100;A		
Contains					

l	Packaging					
l	#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
l	1	NDC:69025-100-01	30 in 1 BOTTLE; Type 0: Not a Combination Product			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
unapproved drug other		0 1/26/20 18			

# TENOFOVIR DISOPROXIL FUMARATE

tenofovir disoproxil fumarate tablet, film coated

Product Information				
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:69025-101	
Route of Administration	ORAL			

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
tenofovir disoproxil fumarate (UNII: OTT9J7900I) (tenofovir anhydrous - UNII:W4HFE001U5)	teno fo vir diso pro xil fumarate	200 mg			

Product Characteristics						
Color	white	Score	no score			
Shape	ROUND	Size	11mm			
Flavor		Imprint Code	10 1;A			
Contains						

P	Packaging					
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date		
1 NDC:69025-101-01 30 in 1 BOTTLE; Type 0: Not a Combination Product						
N	Marketing Information					

Application Number or Monograph Citation

Marketing End Date

Marketing Start Date

01/26/2018

## TENOFOVIR DISOPROXIL FUMARATE

tenofovir disoproxil fumarate tablet, film coated

**Marketing Category** 

unapproved drug other

Product Information					
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:69025-102		
Route of Administration	ORAL				

Active Ingredient/Active Moiety				
l	Ingredient Name	Basis of Strength	Strength	
	tenofovir disoproxil fumarate (UNII: OTT9J7900I) (tenofovir anhydrous - UNII:W4HFE001U5)	tenofovir disoproxil fumarate	250 mg	

Product Characteristics					
Color	white	Score	no score		
Shape	CAPSULE	Size	17mm		
Flavor		Imprint Code	102;A		
Contains					

	Packaging					
l	# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>		
l	1 NDC:69025-102-01	30 in 1 BOTTLE; Type 0: Not a Combination Product				

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		0 1/26/20 18	

# TENOFOVIR DISOPROXIL FUMARATE

tenofovir disoproxil fumarate tablet, film coated

## **Product Information**

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:69025-103
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
tenofovir disoproxil fumarate (UNII: OTT9J79001) (tenofovir anhydrous - UNII:W4HFE001U5)	tenofovir disoproxil fumarate	300 mg	

Product Characteristics			
Color	BLUE (light blue)	Score	no score
Shape	FREEFORM (almond-shaped)	Size	17mm
Flavor		Imprint Code	103;A
Contains			

l	Packaging				
l	# Ite	em Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
l	1 NDC:6	9025-103-01	30 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		0 1/26/20 18	

# Labeler - AIZANT DRUG RESEARCH SOLUTIONS PVT LTD (650372951)

**Registrant -** AIZANT DRUG RESEARCH SOLUTIONS PVT LTD (650372951)

Revised: 8/2015 AIZANT DRUG RESEARCH SOLUTIONS PVT LTD