

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

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

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

Tenofovir disoproxil tablets, 300 mg, are almond-shaped, light blue, film-coated tablets containing 300 mg of tenofovir disoproxil fumarate, which is equivalent to 245 mg of tenofovir disoproxil, are debossed with "103" on one side and "A" on the other side. Each bottle contains 30 tablets, 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**

Each tablet contains 150 mg of tenofovir disoproxil fumarate, which is equivalent to 123 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 Pvt. Ltd.  
Survey No. 172 / 173, Apparel Park Road, Dulapally Village, Qutbullaphur Mandal Hyderabad 500014  
Andhra Pradesh, India  
Made in India  
Mfg. Lic. No.:

NDC 69025-100-01

**Tenofovir Disoproxil Fumarate Tablets**

**150 mg**

**30 tablets**

**Rx only**



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Lot:

Exp:

BARCODE TO BE PROVIDED

**Tenofovir Disoproxil Fumarate Tablets**

NDC 69025-101-01

200 mg - 30 Tablets

Rx only

**Tenofovir Disoproxil Fumarate Tablets**

Each tablet contains 200 mg of tenofovir disoproxil fumarate, which is equivalent to 163 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:**  
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Survey No. 172 / 173, Apparel Park Road, Dulapally Village, Qutbullaphur Mandal Hyderabad 500014  
Andhra Pradesh, India  
Made in India  
Mfg. Lic. No.:

NDC 69025-101-01

**Tenofovir Disoproxil Fumarate Tablets**

**200 mg**

**30 tablets**

**Rx only**



© Aizant Drug Research Solutions Pvt. Ltd.



Lot:

Exp:

BARCODE TO BE PROVIDED

**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 Pvt. Ltd.  
 Survey No. 172 / 173, Apparel Park Road, Dulapally Village, Qutbullapur Mandal Hyderabad 500014  
 Andhra Pradesh, India  
 Made in India  
 Mfg. Lic. No.:

NDC 69025-102-01

**Tenofovir Disoproxil Fumarate Tablets**

**250 mg**

**30 tablets**      **Rx only**

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Lot:      Exp:

BARCODE TO BE PROVIDED

**Tenofovir Disoproxil Fumarate Tablets**

NDC 69025-103-01

300 mg - 30 Tablets

Rx only

**Tenofovir Disoproxil Fumarate Tablets**  
 Each tablet contains 300 mg of tenofovir disoproxil fumarate, which is equivalent to 245 mg of tenofovir disoproxil.  
 Store at 25 °C (77 °F) (see insert).  
 Keep container tightly closed. Dispense only in original container.  
 See package insert for dosage and administration.  
**Manufactured by:**  
 Aizant Drug Research Solutions Pvt. Ltd.  
 Survey No. 172 / 173, Apparel Park Road, Dulapally Village, Qutbullapur Mandal Hyderabad 500014  
 Andhra Pradesh, India  
 Made in India  
 Mfg. Lic. No.:

NDC 69025-103-01

**Tenofovir Disoproxil Fumarate Tablets, 300 mg**

**30 tablets**

**Rx only**

Aizant®  
 © Aizant Drug Research Solutions Pvt. Ltd.

Lot:      Exp:

BARCODE TO BE PROVIDED

**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		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
tenofovir disoproxil fumarate (UNII: OTT9J7900I) (tenofovir anhydrous - UNII:W4HFE001U5)	tenofovir disoproxil fumarate	150 mg

**Product Characteristics**

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

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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		01/26/2018	

**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)	tenofovir disoproxil fumarate	200 mg

**Product Characteristics**

Color	white	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	101;A
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69025-101-01	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		01/26/2018	

**TENOFOVIR DISOPROXIL FUMARATE**

tenofovir disoproxil fumarate tablet, film coated

**Product Information**

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:69025-102
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	250 mg

**Product Characteristics**

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

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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		01/26/2018	

**TENOFOVIR DISOPROXIL FUMARATE**

tenofovir disoproxil fumarate tablet, film coated

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:69025-103	
<b>Route of Administration</b>	ORAL			
<b>Active Ingredient/Active Moiety</b>				
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	
	tenofovir disoproxil fumarate (UNII: OTT9J7900I) (tenofovir anhydrous - UNII:W4HFE001U5)	tenofovir disoproxil fumarate	300 mg	
<b>Product Characteristics</b>				
<b>Color</b>	BLUE (light blue)	<b>Score</b>	no score	
<b>Shape</b>	FREEFORM (almond-shaped)	<b>Size</b>	17mm	
<b>Flavor</b>		<b>Imprint Code</b>	103;A	
<b>Contains</b>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:69025-103-01	30 in 1 BOTTLE; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
unapproved drug other		01/26/2018		

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

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

Revised: 8/2015

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