

ATAZANAVIR- atazanavir capsule
Cadila Healthcare Limited

Atazanavir Capsules

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1591-6 in bottle of 60 Capsules

Atazanavir Capsules, 150 mg

Rx only

60 Capsules



NDC 70771-1592-6 in bottle of 60 Capsules

Atazanavir Capsules, 200 mg

Rx only

60 Capsules



Over Coding Template
No Varnished Area (Do Not Print)
(18 x 41 mm)

NDC 70771-1592-6

Atazanavir Capsules

200 mg

Note to pharmacist: Do not cover ALERT box with pharmacy label.

ALERT: Find out about medicines that should NOT be taken with Atazanavir Capsules.

zydus
pharmaceuticals

60 Capsules
Rx only

Each capsule contains Atazanavir Sulfate equivalent to 200 mg of Atazanavir.

See accompanying package insert for indications and dosage information.

Store at 25°C (77°F); excursions permitted from 15°C to 30°C (59°F to 86°F). [See USP Controlled Room Temperature].

Keep this and all drugs out of the reach of children.

Do not use if inner seal of bottle is broken or missing.

Manufactured by:
Cadila Healthcare Ltd.
Matoda, Ahmedabad, India

Rev: 09/20

95 mm

41 mm

NDC 70771-1593-3 in bottle of 30 Capsules

Atazanavir Capsules, 300 mg

Rx only

30 Capsules



Over Coding Template
No Varnished Area (Do Not Print)
(18 x 41 mm)

NDC 70771-1593-3

Atazanavir Capsules

300 mg

Note to pharmacist: Do no cover ALERT box with pharmacy label.

ALERT: Find out about medicines that should NOT be taken with Atazanavir Capsules.

zydus
pharmaceuticals

30 Capsules
Rx only

Each capsule contains Atazanavir Sulfate equivalent to 300 mg of Atazanavir.

See accompanying package insert for indications and dosage information.

Store at 25°C (77°F); excursions permitted from 15°C to 30°C (59°F to 86°F). [See USP Controlled Room Temperature].

Keep this and all drugs out of the reach of children.

Do not use if inner seal of bottle is broken or missing.

Manufactured by:
Cadila Healthcare Ltd.
Matoda, Ahmedabad, India

Rev: 06/20

95 mm

41 mm

ATAZANAVIR

atazanavir capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1591
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ATAZANAVIR SULFATE (UNII: 4MT4VIE29P) (ATAZANAVIR - UNII:QZU4H47A3S)	ATAZANAVIR	150 mg

Inactive Ingredients

Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSPVIDONE (UNII: 2S7830E561)	
TALC (UNII: 7SEV7J4R1U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
GELATIN (UNII: 2G86QN327L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
ALCOHOL (UNII: 3K9958V90M)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B71O)	
AMMONIA (UNII: 5138Q19F1X)	

Product Characteristics

Color	BLUE (opaque blue) , GRAY (grey opaque)	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	1050
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1591-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	05/04/2021	
2	NDC:70771-1591-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/04/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210575	05/04/2021	

ATAZANAVIR

atazanavir capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1592
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ATAZANAVIR SULFATE (UNII: 4MT4VIE29P) (ATAZANAVIR - UNII:QZU4H47A3S)	ATAZANAVIR	200 mg

Inactive Ingredients

Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSPROVIDONE (UNII: 2S7830E561)	
TALC (UNII: 7SEV7J4R1U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
GELATIN (UNII: 2G86QN327L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
ALCOHOL (UNII: 3K9958V90M)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B71O)	
AMMONIA (UNII: 5138Q19F1X)	

Product Characteristics

Color	BLUE (opaque blue) , BLUE (blue opaque)	Score	no score
Shape	CAPSULE	Size	21mm
Flavor		Imprint Code	1051
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1592-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	05/04/2021	
2	NDC:70771-1592-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/04/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210575	05/04/2021	

ATAZANAVIR

atazanavir capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1593
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ATAZANAVIR SULFATE (UNII: 4MT4VIE29P) (ATAZANAVIR - UNII:QZ U4H47A3S)	ATAZANAVIR	300 mg

Inactive Ingredients

Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSPROVIDONE (UNII: 2S7830E561)	
TALC (UNII: 7SEV7J4R1U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
GELATIN (UNII: 2G86QN327L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
ALCOHOL (UNII: 3K9958V90M)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B71O)	
AMMONIA (UNII: 5138Q19F1X)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Product Characteristics

Color	ORANGE (orange opaque) , BLUE (blue opaque)	Score	no score
Shape	CAPSULE	Size	24mm
Flavor		Imprint Code	1052
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1593-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/04/2021	
2	NDC:70771-1593-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/04/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210575	05/04/2021	

Labeler - Cadila Healthcare Limited (918596198)

Registrant - Cadila Healthcare Limited (863362789)

Establishment

Name	Address	ID/FEI	Business Operations
Cadila Healthcare Limited		863362789	ANALYSIS(70771-1591, 70771-1592, 70771-1593) , MANUFACTURE(70771-1591, 70771-1592, 70771-1593)

Revised: 6/2020

Cadila Healthcare Limited