DROXIDOPA - droxidopa capsule
Zydus Lifesciences Limited

Droxidopa Capsules

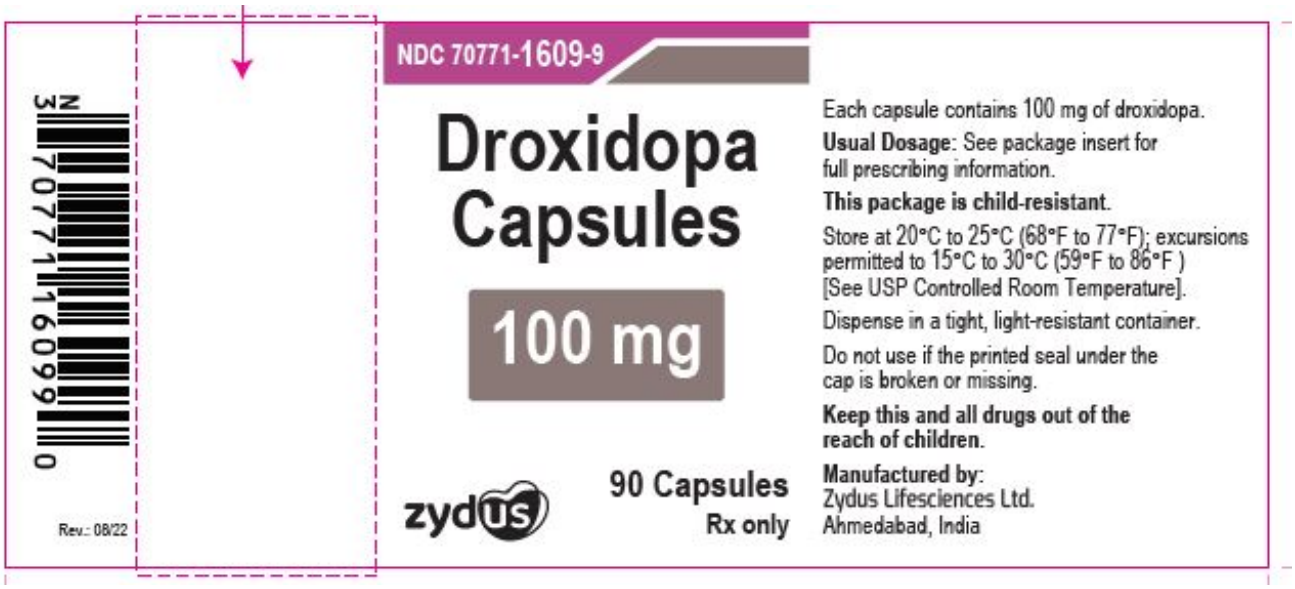
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1609-9

Droxidopa Capsules, 100 mg

90 Capsules

Rx only

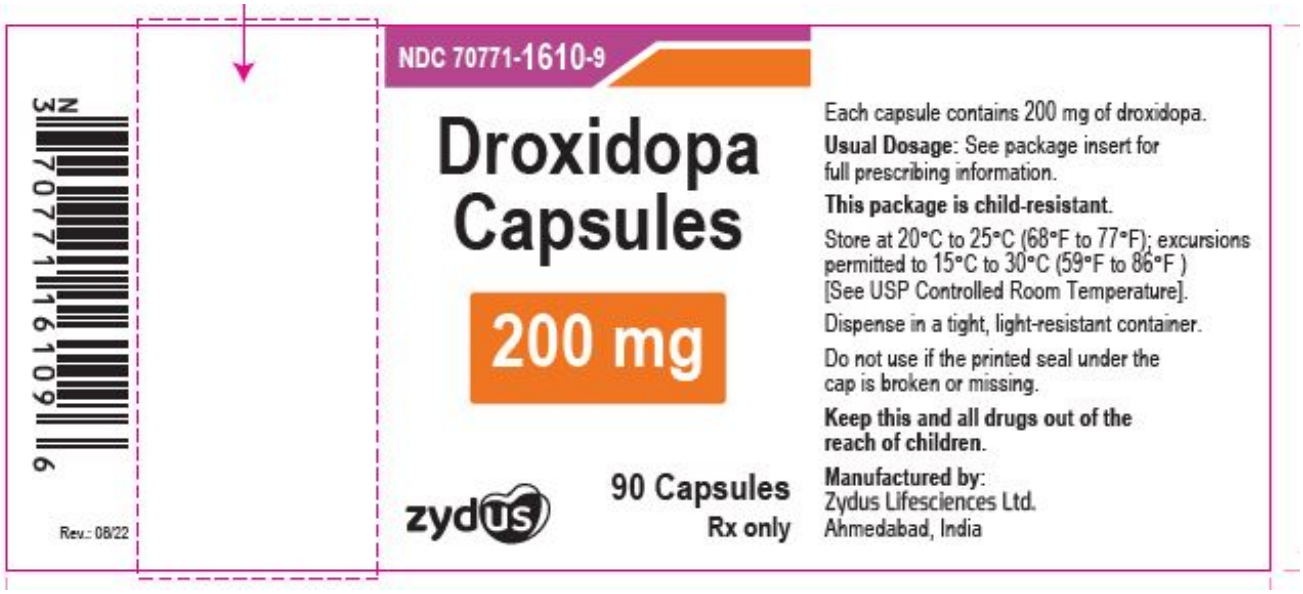


NDC 70771-1610-9

Droxidopa Capsules, 200 mg

90 Capsules

Rx only

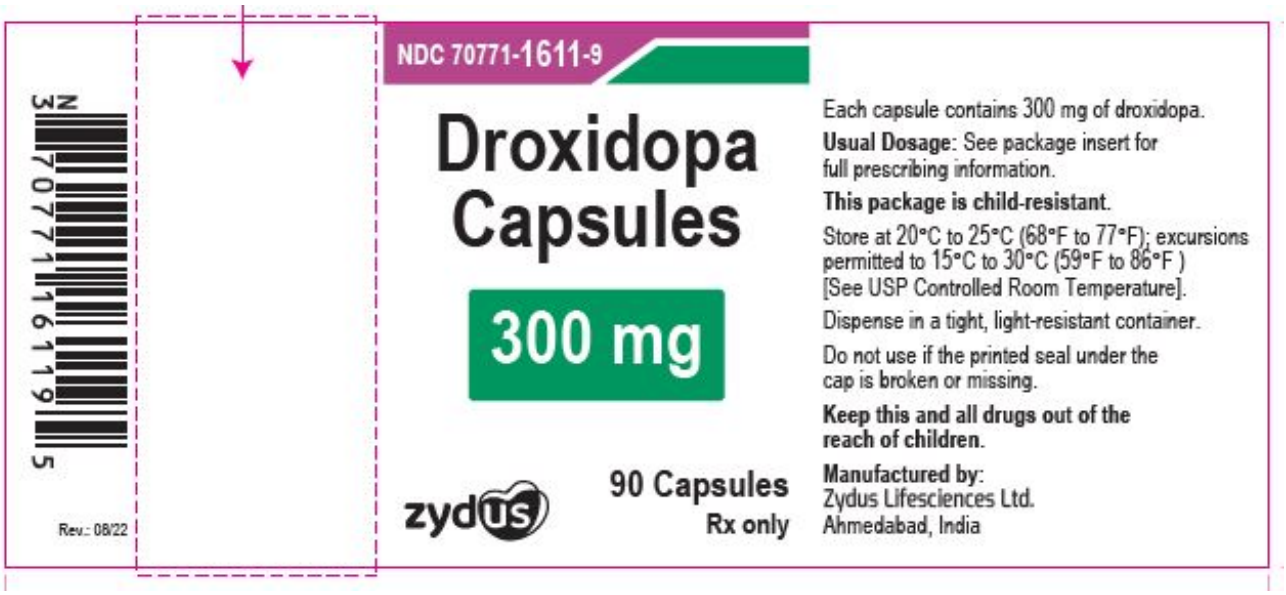


NDC 70771-1611-9

Droxidopa Capsules, 300 mg

90 Capsules

Rx only



DROXIDOPA

droxidopa capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1609
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DROXIDOPA (UNII: J7A92W69L7) (DROXIDOPA - UNII:J7A92W69L7)	DROXIDOPA	100 mg

Inactive Ingredients	
Ingredient Name	**Strength**
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	BLUE (opaque blue cap) , WHITE (opaque white body)	**Score**	no score
Shape	CAPSULE	**Size**	16mm
Flavor		**Imprint Code**	1389
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70771-1609-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	02/19/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211818	02/19/2021	

DROXIDOPA

droxidopa capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1610

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DROXIDOPA (UNII: J7A92W69L7) (DROXIDOPA - UNII:J7A92W69L7)	DROXIDOPA	200 mg

Inactive Ingredients

Ingredient Name	Strength
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	YELLOW (opaque yellow cap) , WHITE (opaque white body)	**Score**	no score
Shape	CAPSULE	**Size**	18mm
Flavor		**Imprint Code**	1390
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1610-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	02/19/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211818	02/19/2021	

DROXIDOPA

droxidopa capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1611
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DROXIDOPA (UNII: J7A92W69L7) (DROXIDOPA - UNII:J7A92W69L7)	DROXIDOPA	300 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	GREEN (opaque green cap) , WHITE (opaque white body)	**Score**	no score
Shape	CAPSULE	**Size**	20mm
Flavor		**Imprint Code**	1391
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1611-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	02/19/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211818	02/19/2021	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (863362789)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1609, 70771-1610, 70771-1611) , MANUFACTURE(70771-1609, 70771-1610, 70771-1611)

Revised: 8/2022 Zydus Lifesciences Limited