

**DROXIDOPA- droxidopa capsule**  
**Zydus Lifesciences Limited**

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**Droxidopa Capsules**

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 70771-1609-9

Droxidopa Capsules, 100 mg

90 Capsules

Rx only

NDC 70771-1609-9

**Droxidopa  
Capsules**

**100 mg**

zydus

90 Capsules  
Rx only

Each capsule contains 100 mg of droxidopa.  
**Usual Dosage:** See package insert for full prescribing information.  
**This package is child-resistant.**  
Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [See USP Controlled Room Temperature].  
Dispense in a tight, light-resistant container.  
Do not use if the printed seal under the cap is broken or missing.  
**Keep this and all drugs out of the reach of children.**  
**Manufactured by:**  
Zydus Lifesciences Ltd.  
Ahmedabad, India

3N  
707711160990

Rev.: 08/22

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

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1609
<b>Route of Administration</b>	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)	
FERROSFERRIC 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
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<b>Route of Administration</b>	ORAL
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### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DROXIDOPA</b> (UNII: J7A92W69L7) (DROXIDOPA - UNII:J7A92W69L7)	DROXIDOPA	200 mg

### Inactive Ingredients

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

### Product Characteristics

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

### 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**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1611
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>DROXIDOPA</b> (UNII: J7A92W69L7) (DROXIDOPA - UNII:J7A92W69L7)	DROXIDOPA	300 mg

**Inactive Ingredients**

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

**Product Characteristics**

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

**Packaging**

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

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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: 11/2024

Zydus Lifesciences Limited