

DIMETHYL FUMARATE - dimethyl fumarate
DIMETHYL FUMARATE- dimethyl fumarate capsule, delayed release
Zydus Lifesciences Limited

DIMETHYL FUMARATE DELAYED-RELEASE CAPSULES

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1532-3

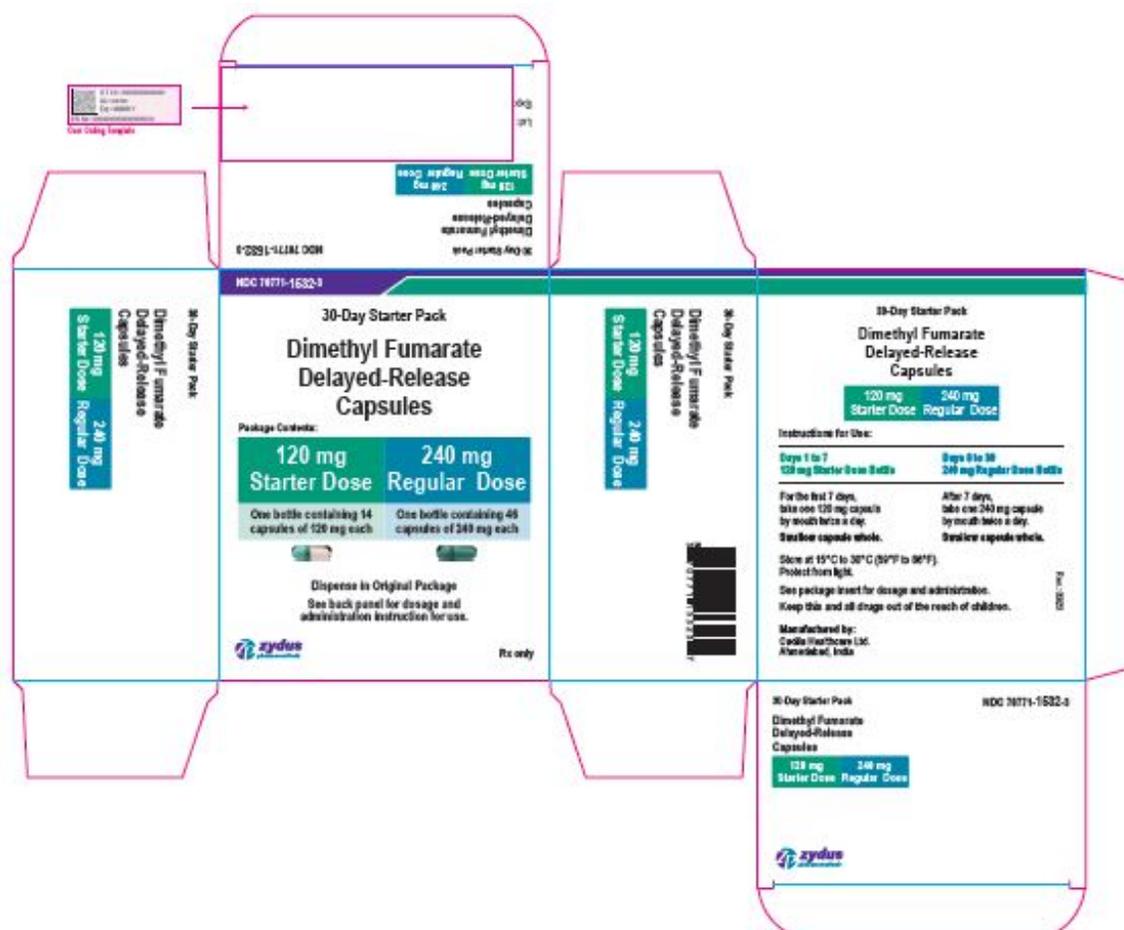
30-Day Starter Pack Carton Label

Dimethyl Fumarate Delayed-release Capsules

120 mg Starter Dose: 14 Capsules

240 mg Regular Dose: 46 Capsules

Rx only



NDC 70771-1530-7

Dimethyl Fumarate Delayed-release Capsules, 120 mg

14 Capsules

Rx only

NDC 70771-1530-7

**Dimethyl Fumarate
Delayed-Release
Capsules**

120 mg

Swallow capsule whole.

14 Capsules
Rx only

Each delayed-release hard gelatin capsule contains dimethyl fumarate, 120 mg.

Dosage: Take one capsule by mouth twice a day.

Store at 15°C to 30°C (59°F to 86°F). Protect from light. Store in original container.

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

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Rev.: 09/20

NDC 70771-1531-6

Dimethyl Fumarate Delayed-release Capsules, 240 mg

60 Capsules

Rx only

NDC 70771-1531-6

**Dimethyl Fumarate
Delayed-Release
Capsules**

240 mg

Swallow capsule whole.

46 Capsules
Rx only

Each delayed-release hard gelatin capsule contains dimethyl fumarate, 240 mg.

Dosage: Take one capsule by mouth twice a day.

Store at 15°C to 30°C (59°F to 86°F). Protect from light. Store in original container.

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

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Rev.: 09/20

DIMETHYL FUMARATE

dimethyl fumarate kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1532
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1532-3	1 in 1 KIT; Type 0: Not a Combination Product	09/28/2020	03/25/2025

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	14
Part 2	1 BOTTLE	46

Part 1 of 2

DIMETHYL FUMARATE

dimethyl fumarate capsule, delayed release

Product Information

Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHYL FUMARATE (UNII: FO2303MNI2) (MONOMETHYL FUMARATE - UNII:45IUB1PX8R)	DIMETHYL FUMARATE	120 mg

Inactive Ingredients

Ingredient Name	Strength
AMMONIA (UNII: 5138Q19F1X)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	

GELATIN (UNII: 2G86QN327L)
GLYCERYL MONO- AND DICAPRYLOCAPRATE (UNII: U72Q2I8C85)
MAGNESIUM STEARATE (UNII: 70097M6I30)
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)
POVIDONE K30 (UNII: U725QWY32X)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHELLAC (UNII: 46N107B71O)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM LAURYL SULFATE (UNII: 368GB5141J)
TALC (UNII: 7SEV7J4R1U)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)

Product Characteristics

Color	GREEN (OPAQUE LIGHT GREEN CAP) , WHITE (OPAQUE WHITE BODY)	Score	no score
Shape	CAPSULE (CAPSULE)	Size	22mm
Flavor		Imprint Code	1204
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210538	09/28/2020	04/01/2025

Part 2 of 2

DIMETHYL FUMARATE

dimethyl fumarate capsule, delayed release

Product Information

Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHYL FUMARATE (UNII: FO2303MNI2) (MONOMETHYL FUMARATE - UNII:45IUB1PX8R)	DIMETHYL FUMARATE	240 mg

Inactive Ingredients

Ingredient Name	Strength
AMMONIA (UNII: 5138Q19F1X)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
GLYCERYL MONO- AND DICAPRYLOCAPRATE (UNII: U72Q2I8C85)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
POVIDONE K30 (UNII: U725QWY32X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B710)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	GREEN (OPAQUE LIGHT GREEN CAP) , GREEN (OPAQUE LIGHT GREEN BODY)	Score	no score
Shape	CAPSULE (CAPSULE)	Size	22mm
Flavor		Imprint Code	1205
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		46 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210538	09/28/2020	04/01/2025

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210538	09/28/2020	04/01/2025

DIMETHYL FUMARATE			
dimethyl fumarate capsule, delayed release			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1530
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
DIMETHYL FUMARATE (UNII: FO2303MNI2) (MONOMETHYL FUMARATE - UNII:45IUB1PX8R)		DIMETHYL FUMARATE	120 mg
Inactive Ingredients			
Ingredient Name			Strength
AMMONIA (UNII: 5138Q19F1X)			
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)			
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
FERRIC OXIDE RED (UNII: 1K09F3G675)			
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)			
FERROSFERRIC OXIDE (UNII: XM0M87F357)			
GELATIN (UNII: 2G86QN327L)			
GLYCERYL MONO- AND DICAPRYLATE (UNII: 34966F76M6)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)			
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)			
POLYSORBATE 80 (UNII: 6OZP39ZG8H)			
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)			
POVIDONE K30 (UNII: U725QWY32X)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
SHELLAC (UNII: 46N107B71O)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			

SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	GREEN (OPAQUE LIGHT GREEN CAP) , WHITE (OPAQUE WHITE BODY)	Score	no score
Shape	CAPSULE (CAPSULE)	Size	22mm
Flavor		Imprint Code	1204
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1530-7	14 in 1 BOTTLE; Type 0: Not a Combination Product	09/28/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210538	09/28/2020	

DIMETHYL FUMARATE

dimethyl fumarate capsule, delayed release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1531
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHYL FUMARATE (UNII: FO2303MNI2) (MONOMETHYL FUMARATE - UNII:45IUB1PX8R)	DIMETHYL FUMARATE	240 mg

Inactive Ingredients

Ingredient Name	Strength
AMMONIA (UNII: 5138Q19F1X)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

FD&C RED NO. 40 (UNII: WZB9127XOA)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
GELATIN (UNII: 2G86QN327L)
GLYCERYL MONO- AND DICAPRYLATE (UNII: 34966F76M6)
MAGNESIUM STEARATE (UNII: 70097M6I30)
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)
POVIDONE K30 (UNII: U725QWY32X)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHELLAC (UNII: 46N107B71O)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM LAURYL SULFATE (UNII: 368GB5141J)
TALC (UNII: 7SEV7J4R1U)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)

Product Characteristics

Color	GREEN (OPAQUE LIGHT GREEN CAP) , GREEN (OPAQUE LIGHT GREEN BODY)	Score	no score
Shape	CAPSULE (CAPSULE)	Size	22mm
Flavor		Imprint Code	1205
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1531-8	46 in 1 BOTTLE; Type 0: Not a Combination Product	09/28/2020	
2	NDC:70771-1531-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	09/28/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210538	09/28/2020	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (863362789)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1530, 70771-1531, 70771-1532) , MANUFACTURE(70771-1530, 70771-1531, 70771-1532)

Revised: 4/2025

Zydus Lifesciences Limited