

IMATINIB MESYLATE- imatinib mesylate tablet, film coated
Cadila Healthcare Limited

Imatinib Mesylate Tablets

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL

NDC 70771-1394-9

Imatinib Mesylate Tablets, 100 mg

90 Tablets

Rx only



NDC 70771-1395-9

Imatinib Mesylate Tablets, 400 mg

90 Tablets

Rx only



IMATINIB MESYLATE

imatinib mesylate tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1394
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IMATINIB MESYLATE (UNII: 8A101M485B) (IMATINIB - UNII:BKJ8M8G5HI)	IMATINIB	100 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	YELLOW (PALE YELLOW TO YELLOW)	Score	2 pieces
Shape	ROUND (ROUND)	Size	9mm
Flavor		Imprint Code	244
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1394-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/21/2021	
2	NDC:70771-1394-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	01/21/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210658	01/21/2021	

IMATINIB MESYLATE

imatinib mesylate tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1395
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IMATINIB MESYLATE (UNII: 8A1O1M485B) (IMATINIB - UNII:BKJ8M8G5HI)	IMATINIB	400 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	YELLOW (PALE YELLOW TO YELLOW)	Score	2 pieces
Shape	OVAL (ovaloid)	Size	19mm
Flavor		Imprint Code	245
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1395-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/21/2021	
2	NDC:70771-1395-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	01/21/2021	
3	NDC:70771-1395-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/21/2021	
4	NDC:70771-1395-8	3 in 1 CARTON	01/21/2021	
4	NDC:70771-1395-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210658	01/21/2021	

Labeler - Cadila Healthcare Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Cadila Healthcare Limited		863362789	ANALYSIS(70771-1394, 70771-1395) , MANUFACTURE(70771-1394, 70771-1395)

Revised: 10/2020

Cadila Healthcare Limited