

**IMATINIB MESYLATE - imatinib mesylate tablet, film coated**  
**Zydus Lifesciences 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

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

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IMATINIB MESYLATE (UNII: 8A1O1M485B) (IMATINIB - UNII:BKJ8M8G5HI)	IMATINIB	100 mg

### Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE (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

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

## 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

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1395
<b>Route of Administration</b>	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 (UNII: 2S7830E561)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ05DW1A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

**TALC** (UNII: 7SEV7J4R1U)

**TITANIUM DIOXIDE** (UNII: 15FIX9V2JP)

### Product Characteristics

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

### 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** - Zydus Lifesciences Limited (918596198)

### Establishment

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

Revised: 10/2022

Zydus Lifesciences Limited