

AZATHIOPRINE - azathioprine tablet
Zydus Lifesciences Limited

Azathioprine Tablets, USP

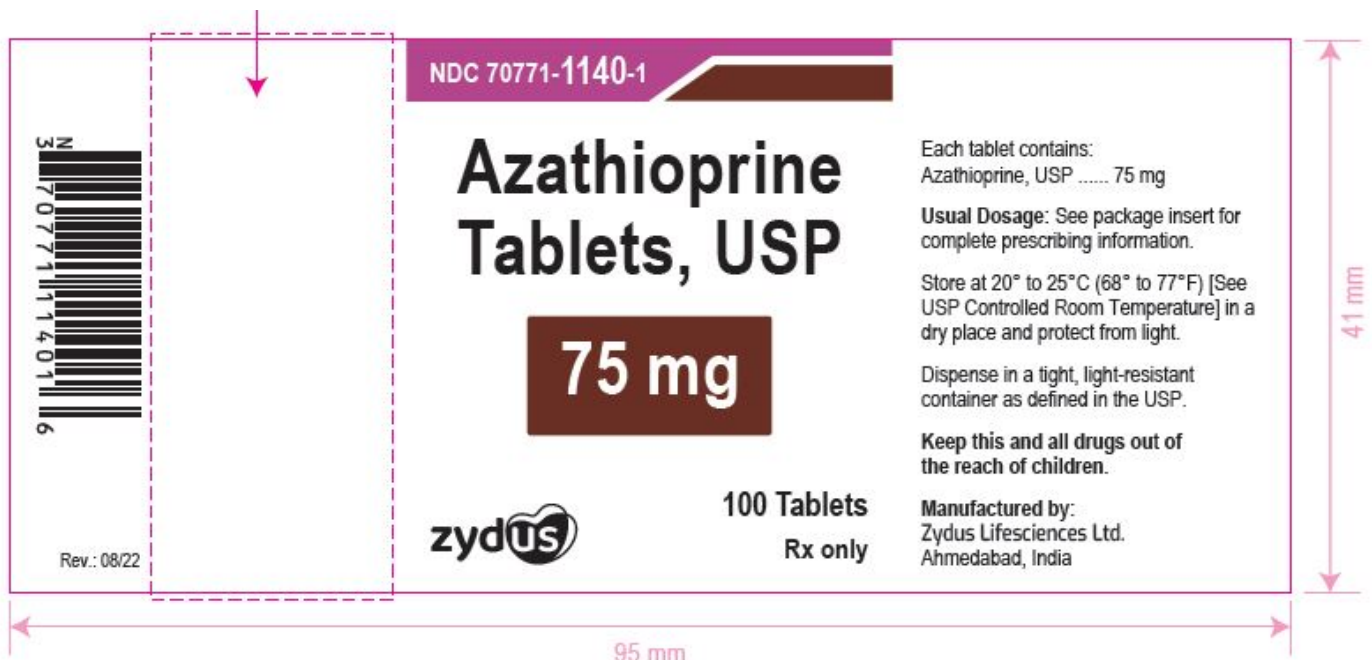
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1140-1 in bottle of 100 tablets

Azathioprine Tablets USP, 75 mg

100 tablets

Rx only



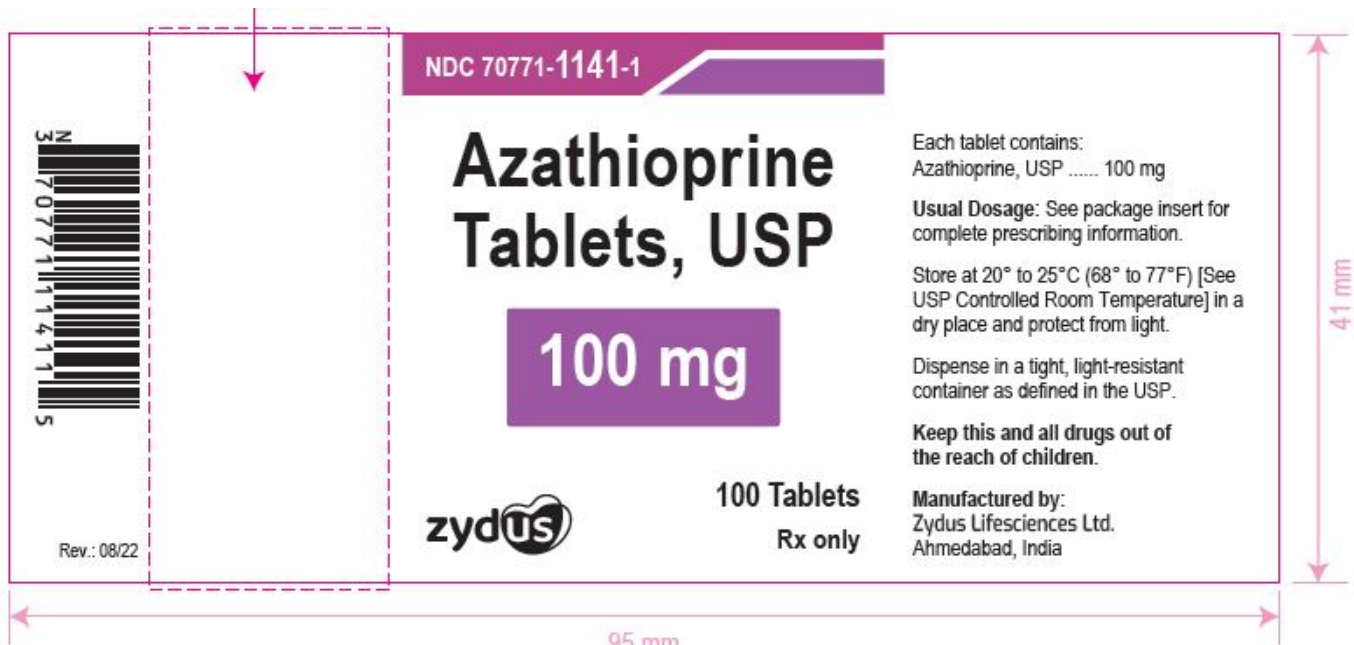
75 mg label

NDC 70771-1141-1 in bottle of 100 tablets

Azathioprine Tablets USP, 100 mg

100 tablets

Rx only



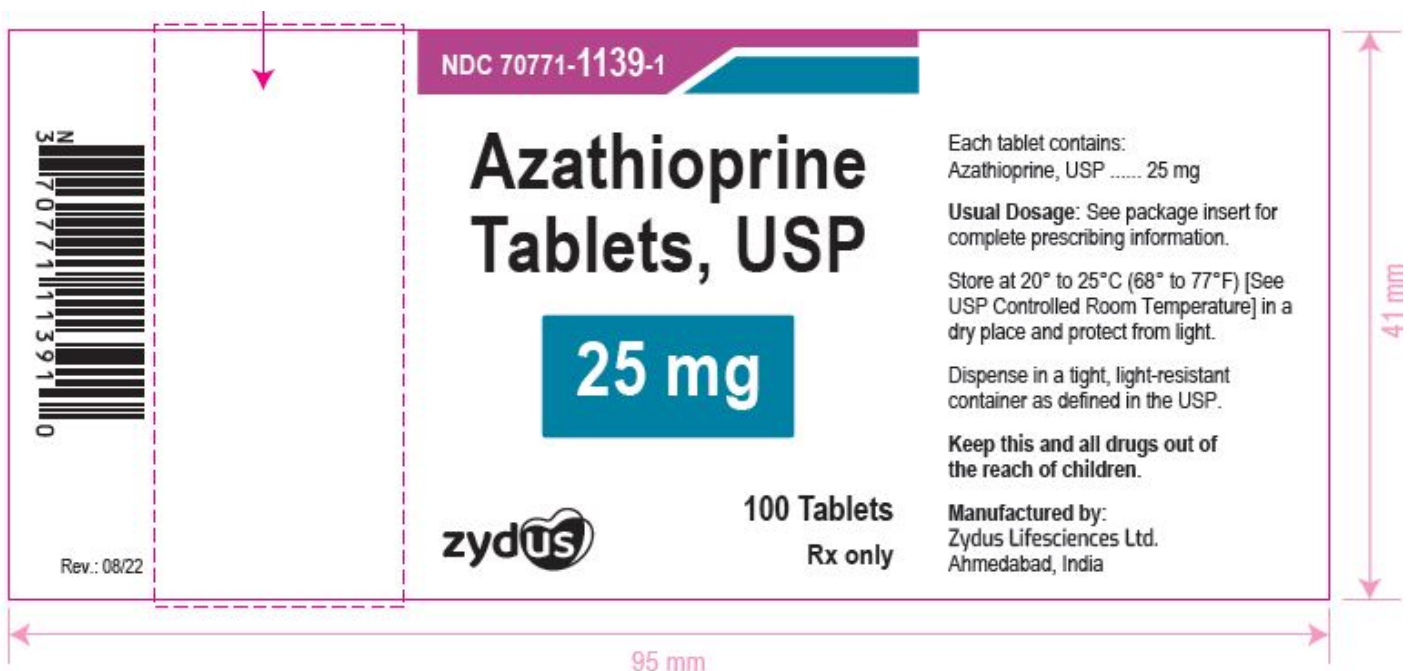
95 mm
100 mg label

NDC 70771-1139-1 in bottle of 100 tablets

Azathioprine Tablets USP, 25 mg

100 tablets

Rx only



95 mm
25 mg label

AZATHIOPRINE

azathioprine tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1139
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AZATHIOPRINE (UNII: MRK240IY2L) (AZATHIOPRINE - UNII:MRK240IY2L)	AZATHIOPRINE	25 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	YELLOW (YELLOW)	Score	2 pieces
Shape	ROUND (ROUND)	Size	6mm
Flavor		Imprint Code	ZD;11
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1139-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/02/2017	
2	NDC:70771-1139-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/02/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077621	12/02/2017	

AZATHIOPRINE

azathioprine tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1140
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Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AZATHIOPRINE (UNII: MRK240IY2L) (AZATHIOPRINE - UNII:MRK240IY2L)	AZATHIOPRINE	75 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	YELLOW (YELLOW)	Score	2 pieces
Shape	ROUND (ROUND)	Size	9mm
Flavor		Imprint Code	ZD;10
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1140-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/02/2017	
2	NDC:70771-1140-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/02/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077621	12/02/2017	

AZATHIOPRINE

azathioprine tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1141
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
AZATHIOPRINE (UNII: MRK240IY2L) (AZATHIOPRINE - UNII:MRK240IY2L)		AZATHIOPRINE	100 mg

Inactive Ingredients		Strength
Ingredient Name		
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)		
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
POVIDONE (UNII: FZ989GH94E)		
STARCH, CORN (UNII: O8232NY3SJ)		

Product Characteristics			
Color	YELLOW (YELLOW)	Score	2 pieces
Shape	ROUND (ROUND)	Size	10mm
Flavor		Imprint Code	ZD;09
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1141-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/02/2017	
2	NDC:70771-1141-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/02/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077621	12/02/2017	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1139, 70771-1140, 70771-1141) , MANUFACTURE(70771-1139, 70771-1140, 70771-1141)