ARIPIPRAZOLE- aripiprazole tablet
Zydus Lifesciences Limited

ARIPIPRAZOLE TABLETS

SPL MEDGUIDE

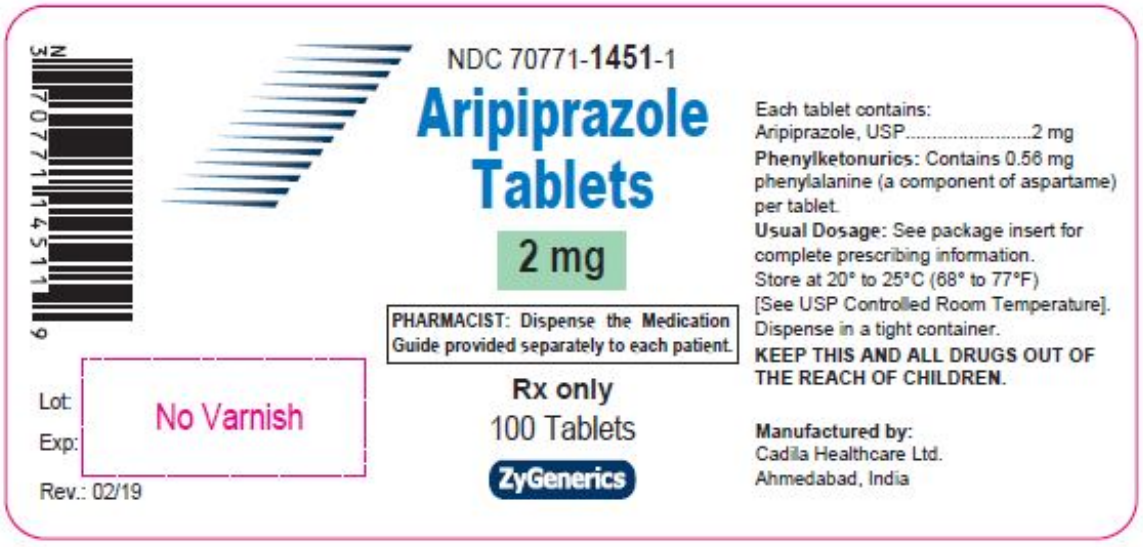
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1451-1

Aripiprazole Tablets, 2 mg

100 tablets

Rx only

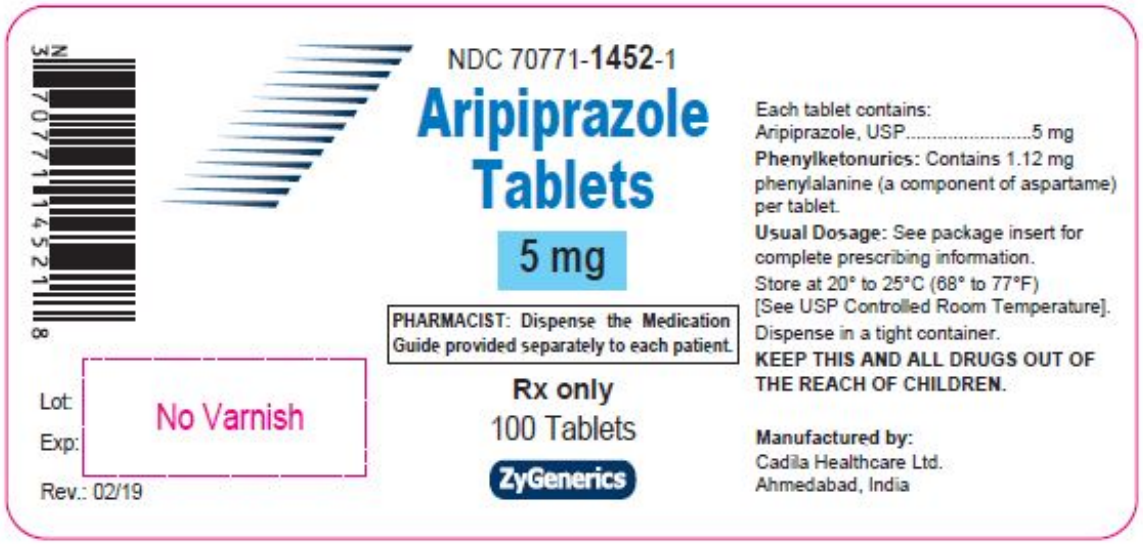


NDC 70771-1452-1

Aripiprazole Tablets, 5 mg

100 tablets

Rx only

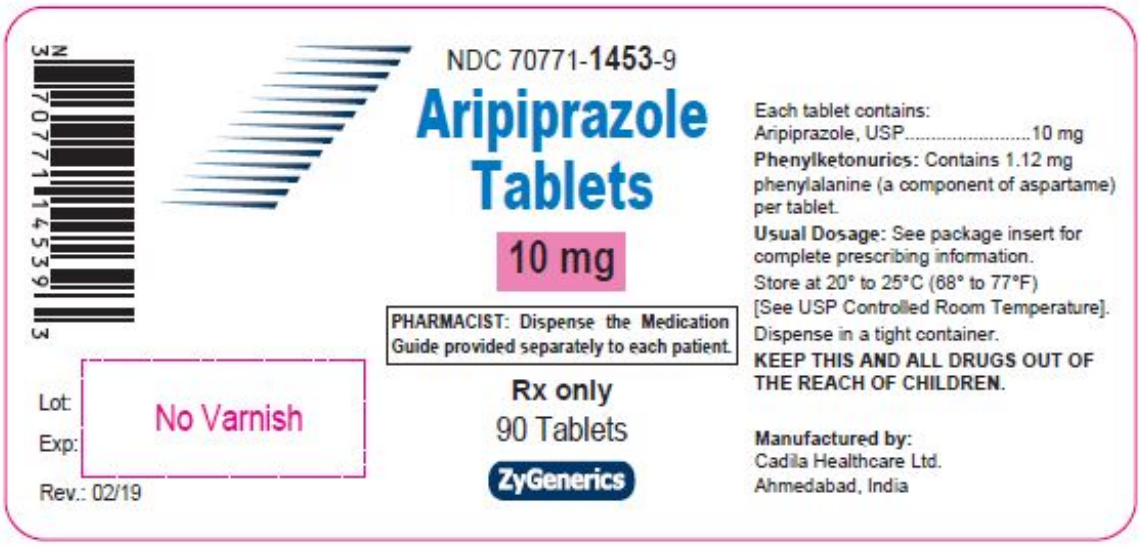


NDC 70771-1453-9

Aripiprazole Tablets, 10 mg

90 tablets

Rx only



NDC 70771-1454-9

Aripiprazole Tablets, 15 mg

90 tablets

Rx only

NDC 70771-1455-9

Aripiprazole Tablets, 20 mg

90 tablets

Rx only

NDC 70771-1456-9

Aripiprazole Tablets, 30 mg

90 tablets

Rx only

ARIPIPRAZOLE

aripiprazole tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1452
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ARIPIPRAZOLE (UNII: 82VFR53I78) (ARIPIPRAZOLE - UNII:82VFR53I78)	ARIPIPRAZOLE	5 mg

Inactive Ingredients

Ingredient Name	Strength
ASPARTAME (UNII: Z0H242BBR1)	
CALCIUM STEARATE (UNII: 776XM7047L)	
CROSPOVIDONE (UNII: 2S7830E561)	
PEPPERMINT (UNII: V95R5KMY2B)	
MANNITOL (UNII: 3OWL53L36A)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	FREEFORM (BARREL)	**Size**	8mm
Flavor	PEPPERMINT (FLAVOR FIRMENICH POWDER PEPPERMINT)	**Imprint Code**	ZE;13
Contains			

Packaging

			Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1452-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2019	
2	NDC:70771-1452-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090472	06/04/2019	

ARIPIPRAZOLE

aripiprazole tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1453
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ARIPIPRAZOLE (UNII: 82VFR53I78) (ARIPIPRAZOLE - UNII:82VFR53I78)	ARIPIPRAZOLE	10 mg

Inactive Ingredients

Ingredient Name	Strength
ASPARTAME (UNII: Z0H242BBR1)	
CALCIUM STEARATE (UNII: 776XM7047L)	
CROSPOVIDONE (UNII: 2S7830E561)	
PEPPERMINT (UNII: V95R5KMY2B)	
MANNITOL (UNII: 3OWL53L36A)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	8mm
Flavor	PEPPERMINT (FLAVOR FIRMENICH POWDER PEPPERMINT)	**Imprint Code**	ZE;4
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1453-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2019	

2	NDC:70771-1453-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2019	
3	NDC:70771-1453-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2019	
4	NDC:70771-1453-7	120 in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2019	
5	NDC:70771-1453-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090472	06/04/2019	

ARIPIPRAZOLE

aripiprazole tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1454
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ARIPIPRAZOLE (UNII: 82VFR53I78) (ARIPIPRAZOLE - UNII:82VFR53I78)	ARIPIPRAZOLE	15 mg

Inactive Ingredients

Ingredient Name	Strength
ASPARTAME (UNII: Z0H242BBR1)	
CALCIUM STEARATE (UNII: 776XM7047L)	
CROSPOVIDONE (UNII: 2S7830E561)	
PEPPERMINT (UNII: V95R5KMY2B)	
MANNITOL (UNII: 3OWL53L36A)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	8mm
Flavor	PEPPERMINT (FLAVOR FIRMENICH POWDER PEPPERMINT)	**Imprint Code**	ZE;14
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:70771-1454-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2019	
2	NDC:70771-1454-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2019	
3	NDC:70771-1454-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2019	
4	NDC:70771-1454-7	120 in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2019	
5	NDC:70771-1454-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090472	06/04/2019	

ARIPIPRAZOLE

aripiprazole tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1455
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ARIPIPRAZOLE (UNII: 82VFR53I78) (ARIPIPRAZOLE - UNII:82VFR53I78)	ARIPIPRAZOLE	20 mg

Inactive Ingredients

Ingredient Name	Strength
ASPARTAME (UNII: Z0H242BBR1)	
CALCIUM STEARATE (UNII: 776XM7047L)	
CROSPOVIDONE (UNII: 2S7830E561)	
PEPPERMINT (UNII: V95R5KMY2B)	
MANNITOL (UNII: 3OWL53L36A)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	FREEFORM (BARREL)	**Size**	10mm
Flavor	PEPPERMINT (FLAVOR FIRMENICH POWDER PEPPERMINT)	**Imprint Code**	ZE;15
Contains			

Packaging

			Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1455-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2019	
2	NDC:70771-1455-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2019	
3	NDC:70771-1455-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2019	
4	NDC:70771-1455-7	120 in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2019	
5	NDC:70771-1455-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090472	06/04/2019	

ARIPIPRAZOLE

aripiprazole tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1456
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ARIPIPRAZOLE (UNII: 82VFR53I78) (ARIPIPRAZOLE - UNII:82VFR53I78)	ARIPIPRAZOLE	30 mg

Inactive Ingredients

Ingredient Name	Strength
ASPARTAME (UNII: Z0H242BBR1)	
CALCIUM STEARATE (UNII: 776XM7047L)	
CROSPOVIDONE (UNII: 2S7830E561)	
PEPPERMINT (UNII: V95R5KMY2B)	
MANNITOL (UNII: 3OWL53L36A)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	10mm
Flavor	PEPPERMINT (FLAVOR FIRMENICH POWDER PEPPERMINT)	**Imprint Code**	ZE;16
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1456-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2019	
2	NDC:70771-1456-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2019	
3	NDC:70771-1456-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2019	
4	NDC:70771-1456-7	120 in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2019	
5	NDC:70771-1456-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090472	06/04/2019	

ARIPIPRAZOLE

aripiprazole tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1451
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ARIPIPRAZOLE (UNII: 82VFR53I78) (ARIPIPRAZOLE - UNII:82VFR53I78)	ARIPIPRAZOLE	2 mg

Inactive Ingredients

Ingredient Name	Strength
ASPARTAME (UNII: Z0H242BBR1)	
CALCIUM STEARATE (UNII: 776XM7047L)	
CROSPOVIDONE (UNII: 2S7830E561)	
MANNITOL (UNII: 3OWL53L36A)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	6mm
Flavor		**Imprint Code**	L1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1451-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2019	
2	NDC:70771-1451-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2019	
3	NDC:70771-1451-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2019	
4	NDC:70771-1451-4	10 in 1 CARTON	06/04/2019	
4		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	ANDA090472	06/04/2019	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1451, 70771-1452, 70771-1453, 70771-1454, 70771-1455, 70771-1456) , MANUFACTURE(70771-1451, 70771-1452, 70771-1453, 70771-1454, 70771-1455, 70771-1456)

Revised: 9/2023 Zydus Lifesciences Limited