

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

3 70771 1451 1 9

NDC 70771-1451-1

**Aripiprazole
Tablets**

2 mg

PHARMACIST: Dispense the Medication
Guide provided separately to each patient.

Rx only
100 Tablets

ZyGenerics

Each tablet contains:
Aripiprazole, USP.....2 mg
Phenylketonurics: Contains 0.56 mg
phenylalanine (a component of aspartame)
per tablet.
Usual Dosage: See package insert for
complete prescribing information.
Store at 20° to 25°C (68° to 77°F)
[See USP Controlled Room Temperature].
Dispense in a tight container.
**KEEP THIS AND ALL DRUGS OUT OF
THE REACH OF CHILDREN.**

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Lot:
Exp:
Rev.: 02/19

No Varnish

NDC 70771-1452-1

Aripiprazole Tablets, 5 mg

100 tablets

Rx only

NDC 70771-1452-1

**Aripiprazole
Tablets**

5 mg

PHARMACIST: Dispense the Medication
Guide provided separately to each patient.

Rx only
100 Tablets

ZyGenerics

Each tablet contains:
Aripiprazole, USP.....5 mg
Phenylketonurics: Contains 1.12 mg
phenylalanine (a component of aspartame)
per tablet.
Usual Dosage: See package insert for
complete prescribing information.
Store at 20° to 25°C (68° to 77°F)
[See USP Controlled Room Temperature].
Dispense in a tight container.
**KEEP THIS AND ALL DRUGS OUT OF
THE REACH OF CHILDREN.**

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

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Lot: **No Varnish**
Exp:
Rev.: 02/19

NDC 70771-1453-9

Aripiprazole Tablets, 10 mg

90 tablets

Rx only

NDC 70771-1453-9

**Aripiprazole
Tablets**

10 mg

PHARMACIST: Dispense the Medication
Guide provided separately to each patient.

Rx only
90 Tablets

ZyGenerics

Each tablet contains:
Aripiprazole, USP.....10 mg
Phenylketonurics: Contains 1.12 mg
phenylalanine (a component of aspartame)
per tablet.
Usual Dosage: See package insert for
complete prescribing information.
Store at 20° to 25°C (68° to 77°F)
[See USP Controlled Room Temperature].
Dispense in a tight container.
**KEEP THIS AND ALL DRUGS OUT OF
THE REACH OF CHILDREN.**

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

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Lot: **No Varnish**
Exp:
Rev.: 02/19

NDC 70771-1454-9

Aripiprazole Tablets, 15 mg

90 tablets

Rx only



NDC 70771-1454-9

**Aripiprazole
Tablets**

15 mg

PHARMACIST: Dispense the Medication Guide provided separately to each patient.

Rx only
90 Tablets

ZyGenerics

Each tablet contains:
Aripiprazole, USP.....15 mg
Phenylketonurics: Contains 1.68 mg phenylalanine (a component of aspartame) per tablet.
Usual Dosage: See package insert for complete prescribing information.
Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].
Dispense in a tight container.
KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

3M
7077114549
2

Lot: **No Varnish**
Exp:
Rev.: 02/19

NDC 70771-1455-9
Aripiprazole Tablets, 20 mg
90 tablets
Rx only



NDC 70771-1455-9

**Aripiprazole
Tablets**

20 mg

PHARMACIST: Dispense the Medication Guide provided separately to each patient.

Rx only
90 Tablets

ZyGenerics

Each tablet contains:
Aripiprazole, USP.....20 mg
Phenylketonurics: Contains 2.24 mg phenylalanine (a component of aspartame) per tablet.
Usual Dosage: See package insert for complete prescribing information.
Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].
Dispense in a tight container.
KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

3M
7077114559
1

Lot: **No Varnish**
Exp:
Rev.: 02/19

NDC 70771-1456-9
Aripiprazole Tablets, 30 mg
90 tablets
Rx only



NDC 70771-1456-9

Aripiprazole Tablets

30 mg

PHARMACIST: Dispense the Medication Guide provided separately to each patient.

Rx only
90 Tablets
ZyGenerics

Each tablet contains:
Aripiprazole, USP.....30 mg
Phenylketonurics: Contains 3.36 mg phenylalanine (a component of aspartame) per tablet.
Usual Dosage: See package insert for complete prescribing information.
Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].
Dispense in a tight container.
KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Lot: **No Varnish**
Exp:
Rev.: 02/19

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)			
CROSPVIDONE (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)	
CROSPVIDONE (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)	
CROSPROVIDONE (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
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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)	
CROSPROVIDONE (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)	
CROSPROVIDONE (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	

ARIPRAZOLE

ariprazole 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
ARIPRAZOLE (UNII: 82VFR53I78) (ARIPRAZOLE - UNII:82VFR53I78)	ARIPRAZOLE	2 mg

Inactive Ingredients

Ingredient Name	Strength
ASPARTAME (UNII: Z0H242BBR1)	
CALCIUM STEARATE (UNII: 776XM7047L)	
CROSPVIDONE (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: 11/2024

Zydus Lifesciences Limited