ZIPRASIDONE- ziprasidone capsule
Zydus Lifesciences Limited

ZIPRASIDONE HYDROCHLORIDE CAPSULES

SPL MEDGUIDE

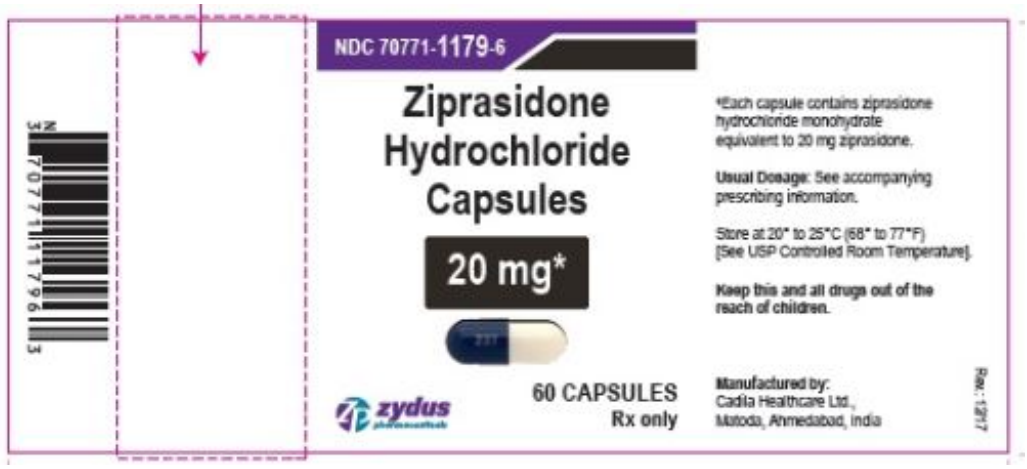
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1179-6

Ziprasidone capsules, 20 mg

60 Capsules

Rx only

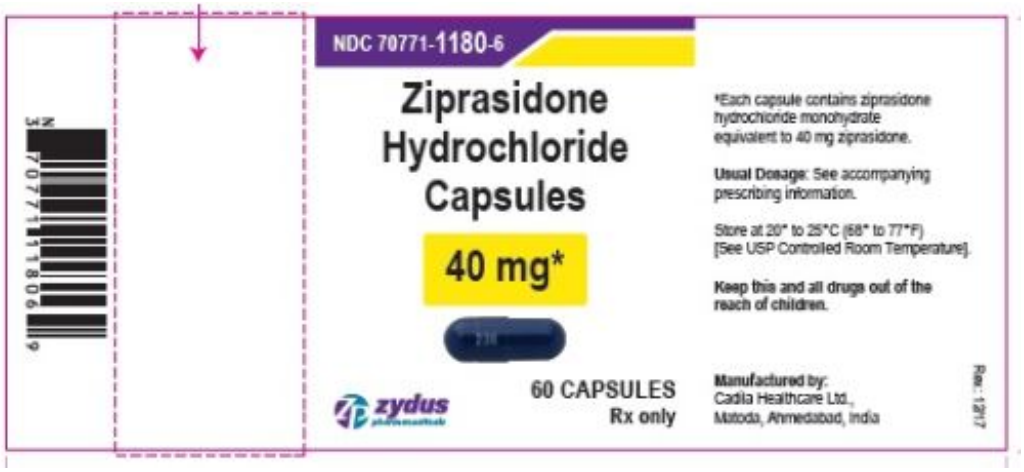


NDC 70771-1180-6

Ziprasidone capsules, 40 mg

60 Capsules

Rx only

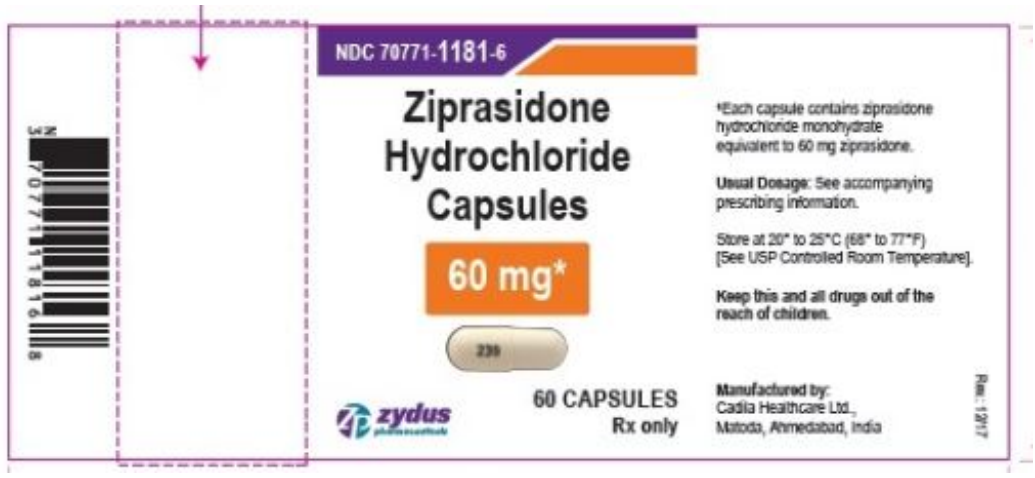


NDC 70771-1181-6

Ziprasidone capsules, 60 mg

60 Capsules

Rx only

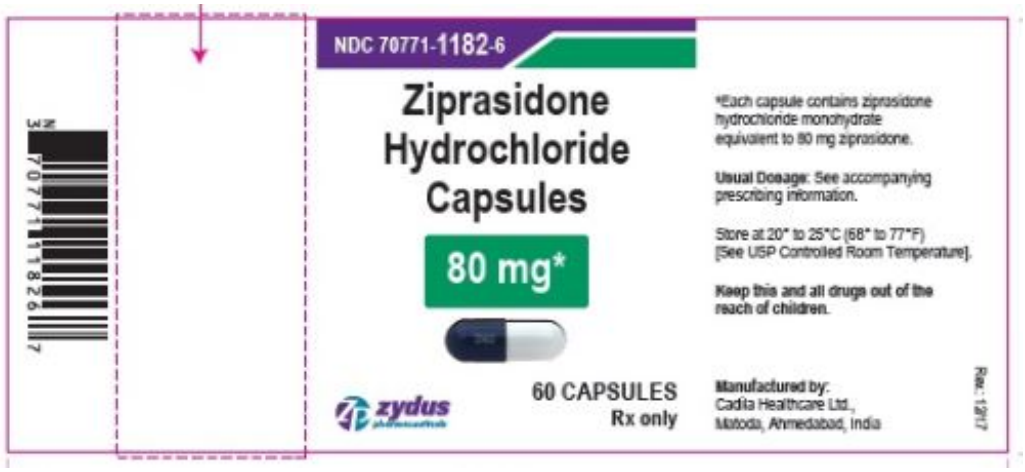


NDC 70771-1182-6

Ziprasidone capsules, 80 mg

60 Capsules

Rx only



ZIPRASIDONE

ziprasidone capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1179
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ZIPRASIDONE HYDROCHLORIDE (UNII: 216X081ORU) (ZIPRASIDONE - UNII:6UKA5VEJ6X)	ZIPRASIDONE	20 mg

Inactive Ingredients	
Ingredient Name	**Strength**
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	BLUE (DARK BLUE OPAQUE CAP) , WHITE (WHITE OPAQUE BODY)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	14mm
Flavor		**Imprint Code**	237

Contains	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1179-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	12/28/2017	
2	NDC:70771-1179-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/28/2017	
3	NDC:70771-1179-8	8 in 1 CARTON	12/28/2017	
3	NDC:70771-1179-2	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	ANDA208988	12/28/2017	

ZIPRASIDONE

ziprasidone capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1180
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZIPRASIDONE HYDROCHLORIDE (UNII: 216X081ORU) (ZIPRASIDONE - UNII:6UKA5VEJ6X)	ZIPRASIDONE	80 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	BLUE (DARK BLUE OPAQUE CAP) , BLUE (LIGHT BLUE OPAQUE BODY)	**Score**	no score
Shape	CAPSULE	**Size**	19mm
Flavor		**Imprint Code**	240
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1180-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	12/28/2017	
2	NDC:70771-1180-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/28/2017	
3	NDC:70771-1180-8	8 in 1 CARTON	12/28/2017	
3	NDC:70771-1180-2	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	ANDA208988	12/28/2017	

ZIPRASIDONE

ziprasidone capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1181
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZIPRASIDONE HYDROCHLORIDE (UNII: 216X081ORU) (ZIPRASIDONE - UNII:6UKA5VEJ6X)	ZIPRASIDONE	60 mg

Inactive Ingredients

Ingredient Name	Strength
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	

MAGNESIUM STEARATE (UNII: 70097M6I30)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (WHITE OPAQUE CAP) , WHITE (WHITE OPAQUE BODY)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	18mm
Flavor		**Imprint Code**	239
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1181-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	12/28/2017	
2	NDC:70771-1181-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/28/2017	
3	NDC:70771-1181-8	8 in 1 CARTON	12/28/2017	
3	NDC:70771-1181-2	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	ANDA208988	12/28/2017	

ZIPRASIDONE

ziprasidone capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1182
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZIPRASIDONE HYDROCHLORIDE (UNII: 216X081ORU) (ZIPRASIDONE - UNII:6UKA5VEJ6X)	ZIPRASIDONE	40 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BLUE (DARK BLUE OPAQUE CAP) , BLUE (LIGHT BLUE OPAQUE BODY)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	16mm
Flavor		**Imprint Code**	238
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1182-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	12/28/2017	
2	NDC:70771-1182-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/28/2017	
3	NDC:70771-1182-8	8 in 1 CARTON	12/28/2017	
3	NDC:70771-1182-2	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	ANDA208988	12/28/2017	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus			ANALYSIS(70771-1179, 70771-1180, 70771-1181, 70771-1182)

Lifesciences Limited		863362789	ANALYSIS(70771-1179, 70771-1180, 70771-1181, 70771-1182) ; MANUFACTURE(70771-1179, 70771-1180, 70771-1181, 70771-1182)