TEMOZOLOMIDE - temozolomide capsule
Zydus Lifesciences Limited

TEMOZOLOMIDE CAPSULES

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1092-6 in bottle of 5 capsules

Temozolomide Capsules, 5 mg

R_x only

5 capsules

NDC 70771-1093-6 in bottle of 5 capsules

Temozolomide Capsules, 20 mg

R_x only

5 capsules

NDC 70771-1094-6 in bottle of 5 capsules

Temozolomide Capsules, 100 mg

R_x only

5 capsules

NDC 70771-1095-6 in bottle of 5 capsules

Temozolomide Capsules, 140 mg

R_x only

5 capsules

NDC 70771-1096-6 in bottle of 5 capsules

Temozolomide Capsules, 180 mg

R_x only

5 capsules

NDC 70771-1097-6 in bottle of 5 capsules

Temozolomide Capsules, 250 mg

R_x only

5 capsules

TEMOZOLOMIDE

temozolomide capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1092
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TEMOZOLOMIDE (UNII: YF1K15M17Y) (TEMOZOLOMIDE - UNII:YF1K15M17Y)	TEMOZOLOMIDE	5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ALCOHOL (UNII: 3K9958V90M)	
AMMONIA (UNII: 5138Q19F1X)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE B POTATO (UNII: 27NA468985)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	GREEN (GREEN) , WHITE (WHITE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	11mm
Flavor		**Imprint Code**	751
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1092-6	5 in 1 BOTTLE; Type 0: Not a Combination Product	10/26/2017	
2	NDC:70771-1092-7	14 in 1 BOTTLE; Type 0: Not a Combination Product	10/26/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206750	10/26/2017	

TEMOZOLOMIDE

temozolomide capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1093
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TEMOZOLOMIDE (UNII: YF1K15M17Y) (TEMOZOLOMIDE - UNII:YF1K15M17Y)	TEMOZOLOMIDE	20 mg

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
AMMONIA (UNII: 5138Q19F1X)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE B POTATO (UNII: 27NA468985)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	YELLOW (YELLOW) , WHITE (WHITE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	11mm
Flavor		**Imprint Code**	752
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1093-6	5 in 1 BOTTLE; Type 0: Not a Combination Product	10/26/2017	
2	NDC:70771-1093-7	14 in 1 BOTTLE; Type 0: Not a Combination Product	10/26/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206750	10/26/2017	

TEMOZOLOMIDE

temozolomide capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1094
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TEMOZOLOMIDE (UNII: YF1K15M17Y) (TEMOZOLOMIDE - UNII:YF1K15M17Y)	TEMOZOLOMIDE	100 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
SODIUM STARCH GLYCOLATE TYPE B POTATO (UNII: 27NA468985)	
TARTARIC ACID (UNII: W4888I119H)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
ALCOHOL (UNII: 3K9958V90M)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
AMMONIA (UNII: 5138Q19F1X)	
WATER (UNII: 059QF0KO0R)	
GELATIN (UNII: 2G86QN327L)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	PINK (PINK) , WHITE (WHITE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	16mm
Flavor		**Imprint Code**	753
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1094-6	5 in 1 BOTTLE; Type 0: Not a Combination Product	10/26/2017	
2	NDC:70771-1094-7	14 in 1 BOTTLE; Type 0: Not a Combination Product	10/26/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206750	10/26/2017	

TEMOZOLOMIDE

temozolomide capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1095
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TEMOZOLOMIDE (UNII: YF1K15M17Y) (TEMOZOLOMIDE - UNII:YF1K15M17Y)	TEMOZOLOMIDE	140 mg

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
AMMONIA (UNII: 5138Q19F1X)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE B POTATO (UNII: 27NA468985)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	BLUE (BLUE) , WHITE (WHITE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	18mm
Flavor		**Imprint Code**	754
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1095-6	5 in 1 BOTTLE; Type 0: Not a Combination Product	10/26/2017	
2	NDC:70771-1095-7	14 in 1 BOTTLE; Type 0: Not a Combination Product	10/26/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206750	10/26/2017	

TEMOZOLOMIDE

temozolomide capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1096
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TEMOZOLOMIDE (UNII: YF1K15M17Y) (TEMOZOLOMIDE - UNII:YF1K15M17Y)	TEMOZOLOMIDE	180 mg

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
AMMONIA (UNII: 5138Q19F1X)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE B POTATO (UNII: 27NA468985)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	ORANGE (ORANGE) , WHITE (WHITE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	21mm
Flavor		**Imprint Code**	755
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1096-6	5 in 1 BOTTLE; Type 0: Not a Combination Product	10/26/2017	
2	NDC:70771-1096-7	14 in 1 BOTTLE; Type 0: Not a Combination Product	10/26/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206750	10/26/2017	

TEMOZOLOMIDE

temozolomide capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1097
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TEMOZOLOMIDE (UNII: YF1K15M17Y) (TEMOZOLOMIDE - UNII:YF1K15M17Y)	TEMOZOLOMIDE	250 mg

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
AMMONIA (UNII: 5138Q19F1X)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE B POTATO (UNII: 27NA468985)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	WHITE (WHITE) , WHITE (WHITE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	24mm
Flavor		**Imprint Code**	756
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1097-6	5 in 1 BOTTLE; Type 0: Not a Combination Product	10/26/2017	
2	NDC:70771-1097-7	14 in 1 BOTTLE; Type 0: Not a Combination Product	10/26/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206750	10/26/2017	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1092, 70771-1093, 70771-1094, 70771-1095, 70771-1096, 70771-1097) , MANUFACTURE(70771-1092, 70771-1093, 70771-1094, 70771-1095, 70771-1096, 70771-1097)

Revised: 10/2022 Zydus Lifesciences Limited