BRIVARACETAM- brivaracetam tablet, film coated
Zydus Lifesciences Limited

BRIVARACETAM tablets, for oral use, CV

SPL MEDGUIDE

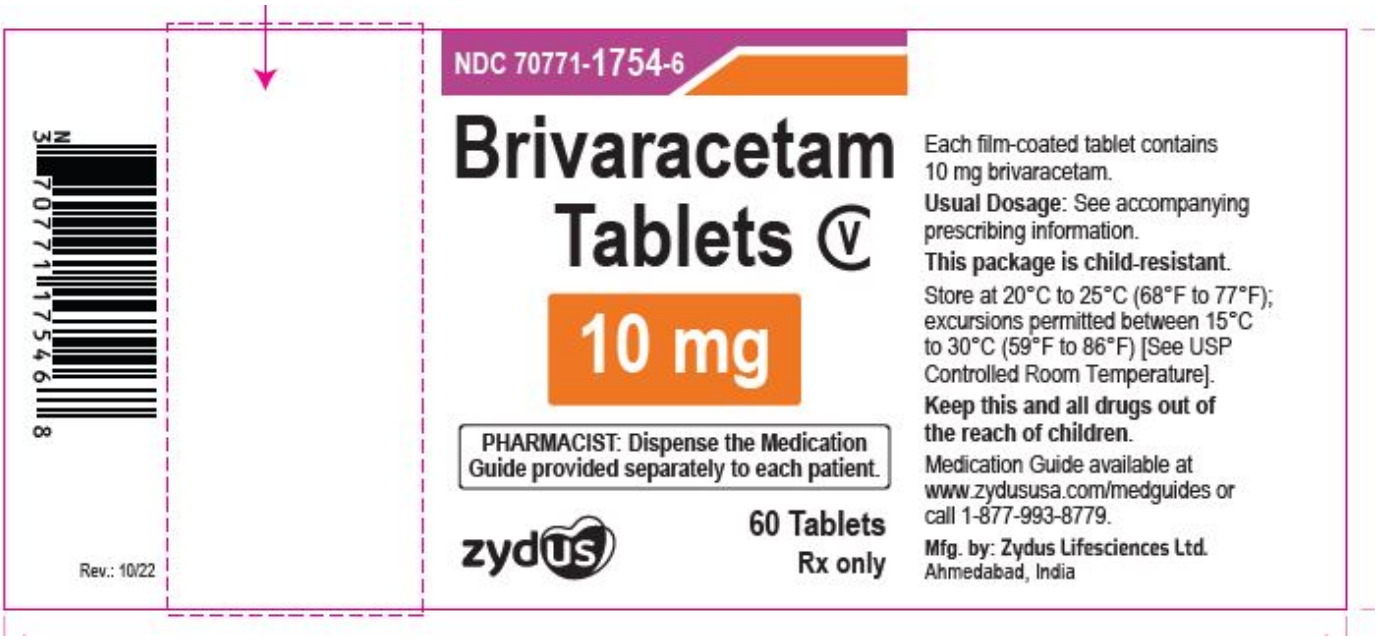
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1754-6

Brivaracetam tablets, 10 mg - CV

60 Tablets

Rx only

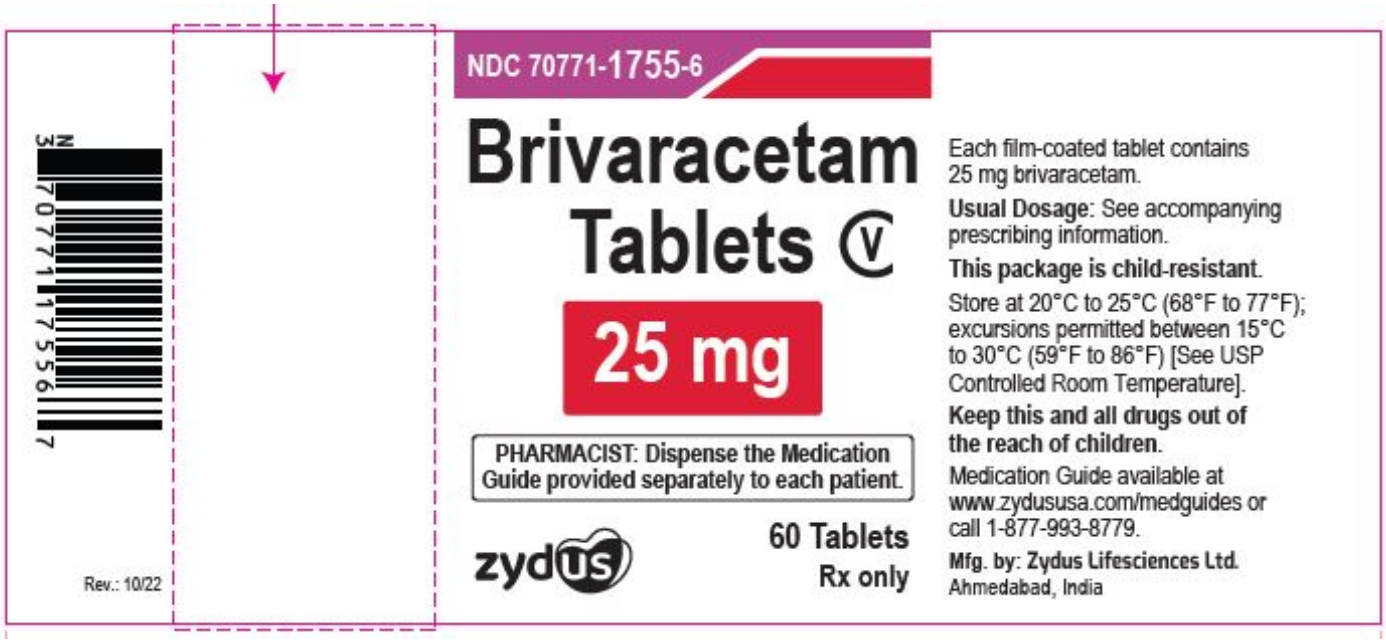


NDC 70771-1755-6

Brivaracetam tablets, 25 mg - CV

60 Tablets

Rx only

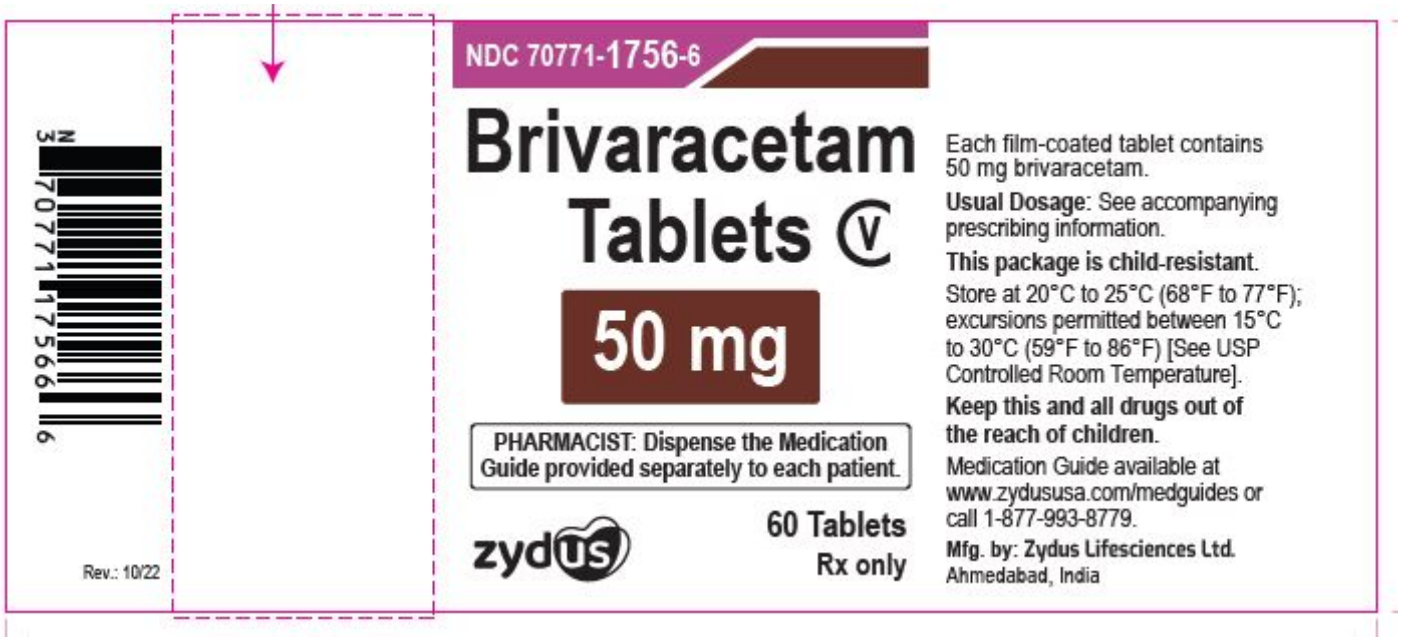


NDC 70771-1756-6

Brivaracetam tablets, 50 mg - CV

60 Tablets

Rx only

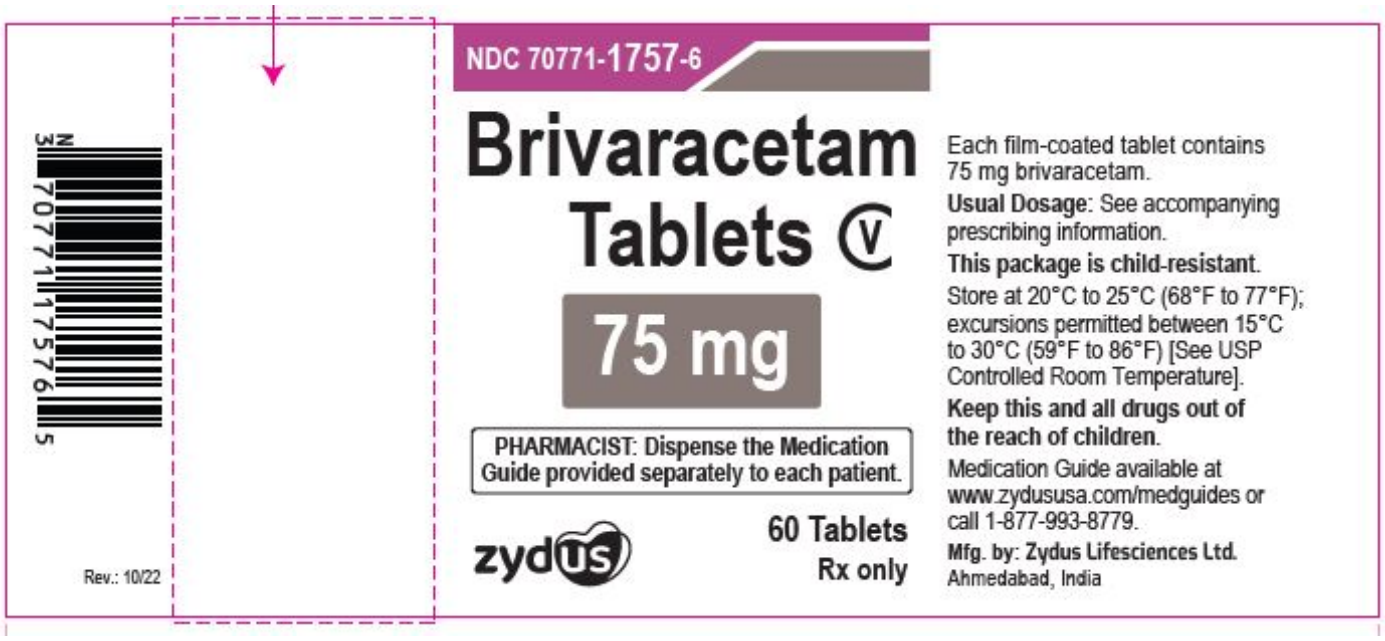


NDC 70771-1757-6

Brivaracetam tablets, 75 mg - CV

60 Tablets

Rx only

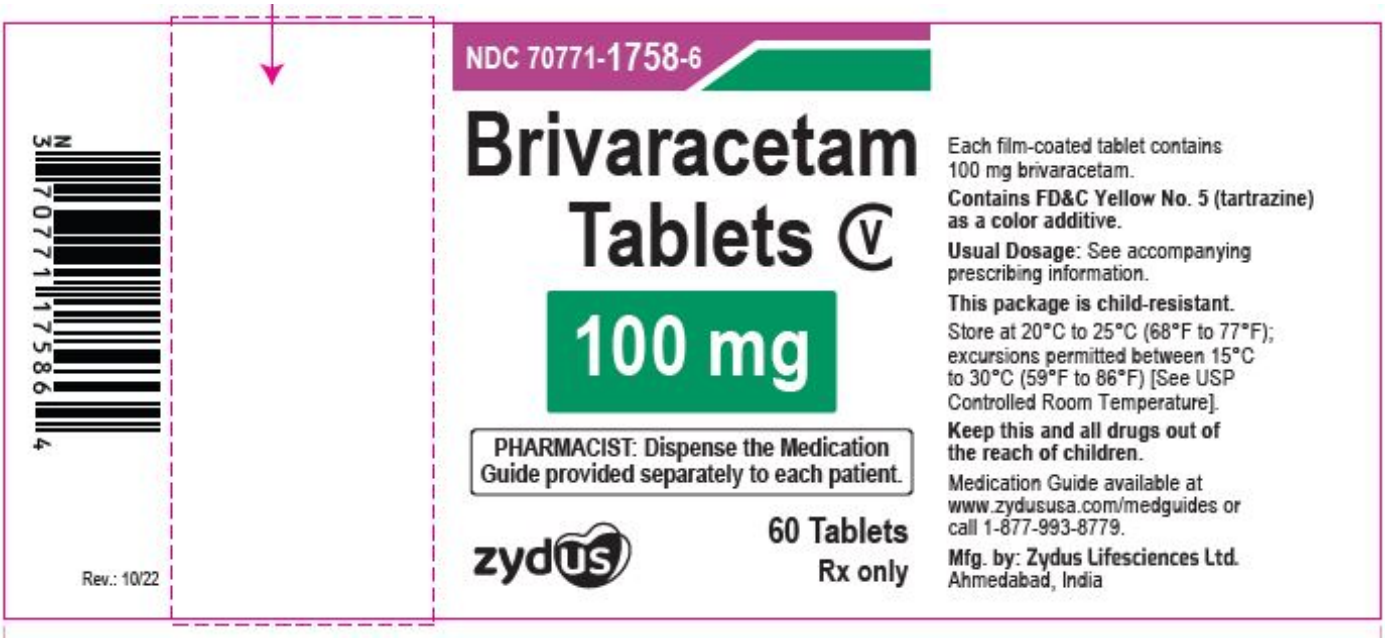


NDC 70771-1758-6

Brivaracetam tablets, 100 mg - CV

60 Tablets

Rx only



BRIVARACETAM

brivaracetam tablet, film coated

Product Information			
	HUMAN PRESCRIPTION		

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1754
Route of Administration	ORAL	**DEA Schedule**	CV

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BRIVARACETAM (UNII: U863JGG2IA) (BRIVARACETAM - UNII:U863JGG2IA)	BRIVARACETAM	10 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
GLYCERYL MONO- AND DICAPRYLOCAPRATE (UNII: U72Q2I8C85)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (off-white)	**Score**	no score
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	U
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1754-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	02/21/2026	
2	NDC:70771-1754-8	180 in 1 BOTTLE; Type 0: Not a Combination Product	02/21/2026	
3	NDC:70771-1754-4	100 in 1 CARTON	02/21/2026	
3	NDC:70771-1754-7	1 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	ANDA214501	02/21/2026	

BRIVARACETAM

brivaracetam tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1755
Route of Administration	ORAL	**DEA Schedule**	CV

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BRIVARACETAM (UNII: U863JGG2IA) (BRIVARACETAM - UNII:U863JGG2IA)	BRIVARACETAM	25 mg

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM OXIDE (UNII: LMI26O6933)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERYL MONO- AND DICAPRYLOCAPRATE (UNII: U72Q2I8C85)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BLUE (light blue)	**Score**	no score
Shape	OVAL	**Size**	9mm
Flavor		**Imprint Code**	U1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1755-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	02/21/2026	
2	NDC:70771-1755-8	180 in 1 BOTTLE; Type 0: Not a Combination Product	02/21/2026	
3	NDC:70771-1755-4	100 in 1 CARTON	02/21/2026	
3	NDC:70771-1755-7	1 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	ANDA214501	02/21/2026	

BRIVARACETAM

brivaracetam tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1756
Route of Administration	ORAL	**DEA Schedule**	CV

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BRIVARACETAM (UNII: U863JGG2IA) (BRIVARACETAM - UNII:U863JGG2IA)	BRIVARACETAM	50 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
GLYCERYL MONO- AND DICAPRYLOCAPRATE (UNII: U72Q2I8C85)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (off-white)	**Score**	no score
Shape	OVAL	**Size**	12mm
Flavor		**Imprint Code**	U11
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1756-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	02/21/2026	
2	NDC:70771-1756-8	180 in 1 BOTTLE; Type 0: Not a Combination Product	02/21/2026	
3	NDC:70771-1756-4	100 in 1 CARTON	02/21/2026	

3	NDC:70771-1756-7	1 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	ANDA214501	02/21/2026	

BRIVARACETAM

brivaracetam tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1757
Route of Administration	ORAL	**DEA Schedule**	CV

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BRIVARACETAM (UNII: U863JGG2IA) (BRIVARACETAM - UNII:U863JGG2IA)	BRIVARACETAM	75 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
BLUE 1 LAKE (UNII: J9EQA3S2JM)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
GLYCERYL MONO- AND DICAPRYLOCAPRATE (UNII: U72Q2I8C85)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	PURPLE	**Score**	no score
Shape	OVAL	**Size**	13mm
Flavor		**Imprint Code**	1587
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1757-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	02/21/2026	
2	NDC:70771-1757-8	180 in 1 BOTTLE; Type 0: Not a Combination Product	02/21/2026	
3	NDC:70771-1757-4	100 in 1 CARTON	02/21/2026	
3	NDC:70771-1757-7	1 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	ANDA214501	02/21/2026	

BRIVARACETAM

brivaracetam tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1758
Route of Administration	ORAL	**DEA Schedule**	CV

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BRIVARACETAM (UNII: U863JGG2IA) (BRIVARACETAM - UNII:U863JGG2IA)	BRIVARACETAM	100 mg

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM OXIDE (UNII: LMI26O6933)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
BLUE 1 LAKE (UNII: J9EQA3S2JM)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
GLYCERYL MONO- AND DICAPRYLOCAPRATE (UNII: U72Q2I8C85)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	GREEN (light-green)	**Score**	no score
Shape	OVAL	**Size**	15mm
Flavor		**Imprint Code**	1588
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1758-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	02/21/2026	
2	NDC:70771-1758-8	180 in 1 BOTTLE; Type 0: Not a Combination Product	02/21/2026	
3	NDC:70771-1758-4	100 in 1 CARTON	02/21/2026	
3	NDC:70771-1758-7	1 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	ANDA214501	02/21/2026	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (863362789)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1754, 70771-1755, 70771-1756, 70771-1757, 70771-1758) , MANUFACTURE(70771-1754, 70771-1755, 70771-1756, 70771-1757, 70771-1758)

Revised: 1/2026 Zydus Lifesciences Limited