

BRIVARACETAM- brivaracetam tablet, film coated
Zydus Lifesciences Limited

BRIVARACETAM tablets, for oral use, CV

SPL MEDGUIDE

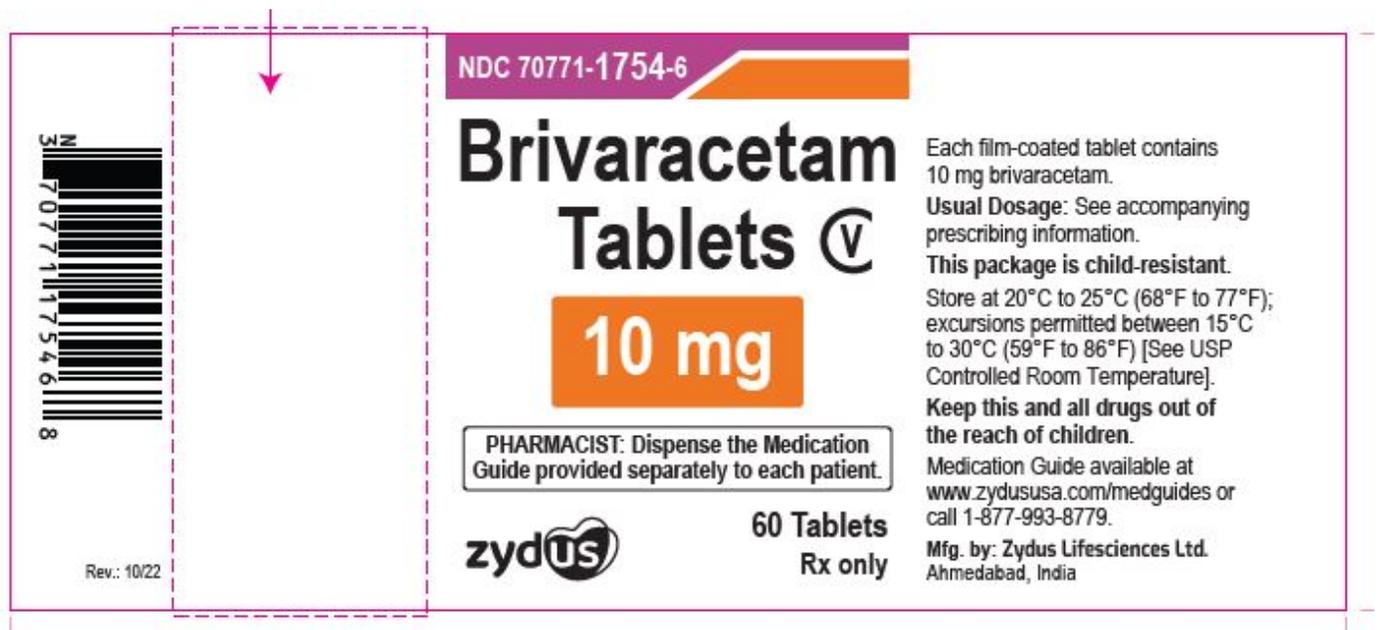
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

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 70771-1755-6

**Brivaracetam
Tablets** 

25 mg

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

zydUS

**60 Tablets
Rx only**

Each film-coated tablet contains 25 mg brivaracetam.
Usual Dosage: See accompanying prescribing information.
This package is child-resistant.
 Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [See USP Controlled Room Temperature].
Keep this and all drugs out of the reach of children.
 Medication Guide available at www.zydususa.com/medguides or call 1-877-993-8779.
 Mfg. by: Zydus Lifesciences Ltd. Ahmedabad, India

Rev.: 10/22

NDC 70771-1756-6
 Brivaracetam tablets, 50 mg - CV
 60 Tablets
 Rx only

NDC 70771-1756-6

**Brivaracetam
Tablets** 

50 mg

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

zydUS

**60 Tablets
Rx only**

Each film-coated tablet contains 50 mg brivaracetam.
Usual Dosage: See accompanying prescribing information.
This package is child-resistant.
 Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [See USP Controlled Room Temperature].
Keep this and all drugs out of the reach of children.
 Medication Guide available at www.zydususa.com/medguides or call 1-877-993-8779.
 Mfg. by: Zydus Lifesciences Ltd. Ahmedabad, India

Rev.: 10/22

NDC 70771-1757-6
 Brivaracetam tablets, 75 mg - CV
 60 Tablets
 Rx only

NDC 70771-1757-6

**Brivaracetam
Tablets **

75 mg

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

 **60 Tablets
Rx only**

Each film-coated tablet contains 75 mg brivaracetam.
Usual Dosage: See accompanying prescribing information.
This package is child-resistant.
 Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [See USP Controlled Room Temperature].
Keep this and all drugs out of the reach of children.
 Medication Guide available at www.zydususa.com/medguides or call 1-877-993-8779.
Mfg. by: Zydus Lifesciences Ltd.
 Ahmedabad, India

Rev.: 10/22

NDC 70771-1758-6

Brivaracetam tablets, 100 mg - CV

60 Tablets

Rx only

NDC 70771-1758-6

**Brivaracetam
Tablets **

100 mg

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

 **60 Tablets
Rx only**

Each film-coated tablet contains 100 mg brivaracetam.
 Contains FD&C Yellow No. 5 (tartrazine) as a color additive.
Usual Dosage: See accompanying prescribing information.
This package is child-resistant.
 Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [See USP Controlled Room Temperature].
Keep this and all drugs out of the reach of children.
 Medication Guide available at www.zydususa.com/medguides or call 1-877-993-8779.
Mfg. by: Zydus Lifesciences Ltd.
 Ahmedabad, India

Rev.: 10/22

BRIVARACETAM

brivaracetam tablet, film coated

Product Information

HUMAN DESCRIPTION

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: U72Q218C85)	
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)	
CROSCARMELOSE 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)	
CROSCARMELOSE 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