

SACUBITRIL AND VALSARTAN- sacubitril and valsartan tablet
Zydus Lifesciences Limited

Sacubitril and Valsartan Tablets

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1921-6

Sacubitril and valsartan tablets, 24 mg/26 mg

60 Tablets

Rx only



Over Coding Template
No Varnished Area (Do Not Print)
(18 x 41 mm)



NDC 70771-1922-6

Sacubitril and valsartan tablets, 49 mg/51 mg

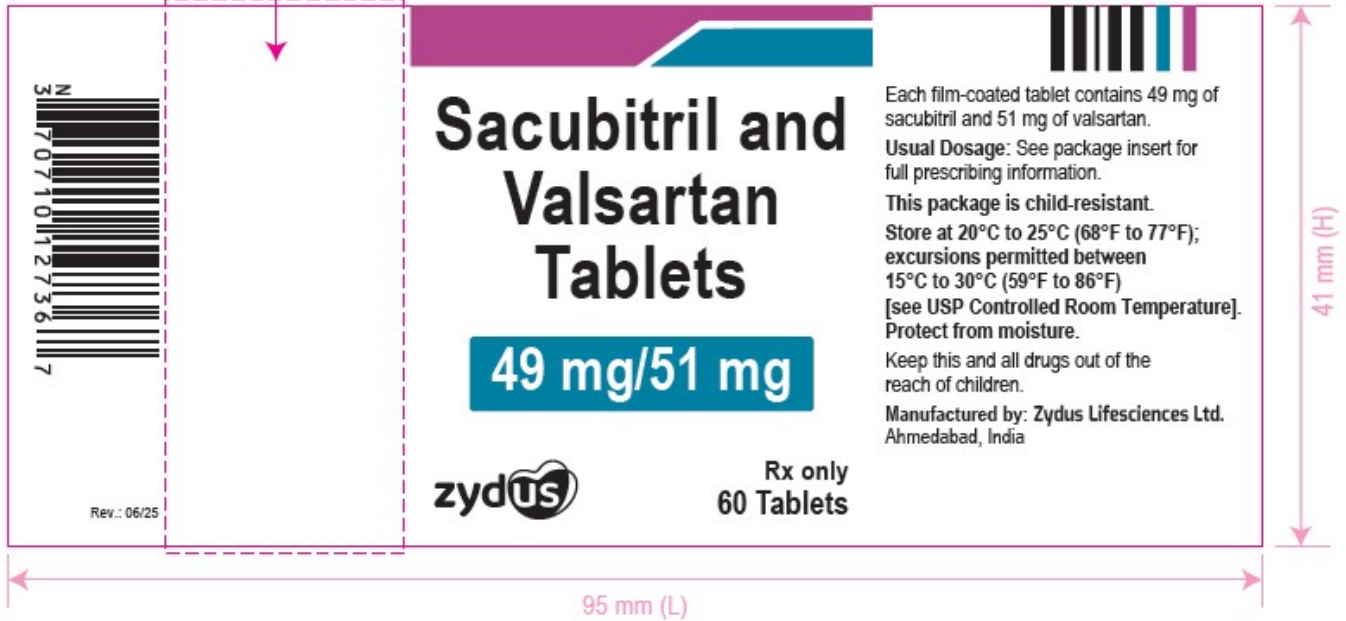
60 Tablets

Rx only



Over Coding Template

No Varnished Area (Do Not Print)
(18 x 41 mm)



NDC 70771-1923-6

Sacubitril and valsartan tablets, 97 mg/103 mg

60 Tablets

Rx only



Over Coding Template

No Varnished Area (Do Not Print)
(18 x 41 mm)

Sacubitril and Valsartan Tablets
97 mg/103 mg

Each film-coated tablet contains 97 mg of sacubitril and 103 mg of valsartan. Contains FD&C Yellow No. 5 (tartrazine) as a color additive.
Usual Dosage: See package insert for full 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].
Protect from moisture.
Keep this and all drugs out of the reach of children.
Manufactured by: Zydus Lifesciences Ltd. Ahmedabad, India

zydus Rx only
60 Tablets

Rev.: 06/25

95 mm (L) 41 mm (H)

SACUBITRIL AND VALSARTAN

sacubitril and valsartan tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1921
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SACUBITRIL (UNII: 17ERJ0MKGI) (SACUBITRILAT - UNII:SPI5PBF81S)	SACUBITRIL	24 mg
VALSARTAN (UNII: 80M03YXJ7I) (VALSARTAN - UNII:80M03YXJ7I)	VALSARTAN	26 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)	
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MICROCRYSTALLINE CELLULOSE 101 (UNII: 7T9FYH5QMK)	
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	WHITE (off-white)	Score	no score
Shape	OVAL	Size	10mm
Flavor		Imprint Code	71
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1921-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	07/08/2025	
2	NDC:70771-1921-8	180 in 1 BOTTLE; Type 0: Not a Combination Product	07/08/2025	
3	NDC:70771-1921-4	10 in 1 CARTON	07/08/2025	
3	NDC:70771-1921-2	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	ANDA213719	07/08/2025	

SACUBITRIL AND VALSARTAN

sacubitril and valsartan tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1922
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SACUBITRIL (UNII: 17ERJ0MKGI) (SACUBITRILAT - UNII:SPI5PBF81S)	SACUBITRIL	49 mg
VALSARTAN (UNII: 80M03YXJ7I) (VALSARTAN - UNII:80M03YXJ7I)	VALSARTAN	51 mg

Inactive Ingredients	
Ingredient Name	Strength
CROSPVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)	

FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14)
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)
MICROCRYSTALLINE CELLULOSE 101 (UNII: 7T9FYH5QMK)
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics			
Color	BROWN (dark-brown)	Score	no score
Shape	OVAL	Size	13mm
Flavor		Imprint Code	72
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1922-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	07/08/2025	
2	NDC:70771-1922-8	180 in 1 BOTTLE; Type 0: Not a Combination Product	07/08/2025	
3	NDC:70771-1922-4	10 in 1 CARTON	07/08/2025	
3	NDC:70771-1922-2	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	ANDA213719	07/08/2025	

SACUBITRIL AND VALSARTAN			
sacubitril and valsartan tablet			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1923
Route of Administration	ORAL		
Active Ingredient/Active Moiety			

Ingredient Name	Basis of Strength	Strength
SACUBITRIL (UNII: 17ERJ0MKGI) (SACUBITRILAT - UNII:SPI5PBF81S)	SACUBITRIL	97 mg
VALSARTAN (UNII: 80M03YXJ7I) (VALSARTAN - UNII:80M03YXJ7I)	VALSARTAN	103 mg

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM OXIDE (UNII: LMI26O6933)	
CROSPROVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)	
FD&C BLUE NO. 2--ALUMINUM LAKE (UNII: 4AQJ3LG584)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MICROCRYSTALLINE CELLULOSE 101 (UNII: 7T9FYH5QMK)	
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	ORANGE (light orange to orange)	Score	no score
Shape	OVAL	Size	15mm
Flavor		Imprint Code	73
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1923-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	07/08/2025	
2	NDC:70771-1923-8	180 in 1 BOTTLE; Type 0: Not a Combination Product	07/08/2025	
3	NDC:70771-1923-4	10 in 1 CARTON	07/08/2025	
3	NDC:70771-1923-2	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	ANDA213719	07/08/2025	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1921, 70771-1922, 70771-1923) , MANUFACTURE(70771-1921, 70771-1922, 70771-1923)

Revised: 7/2025

Zydus Lifesciences Limited