OLMESARTAN MEDOXOMIL - olmesartan medoxomil tablet, film coated
Zydus Lifesciences Limited

OLMESARTAN MEDOXOMIL TABLETS

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1059-1

Olmesartan Medoxomil Tablets, 5 mg

Rx only

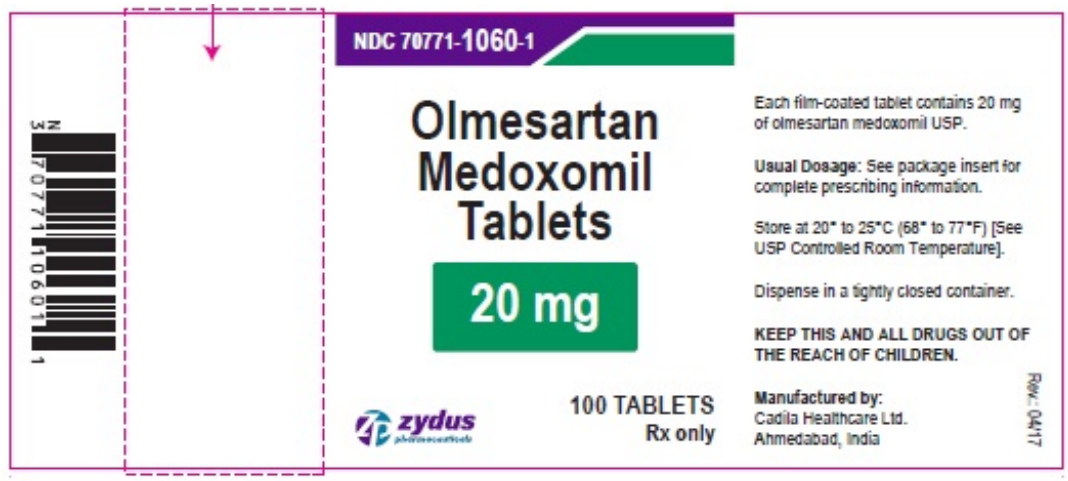
100 TABLETS

NDC 70771-1060-1

Olmesartan Medoxomil Tablets, 20 mg

Rx only

100 TABLETS

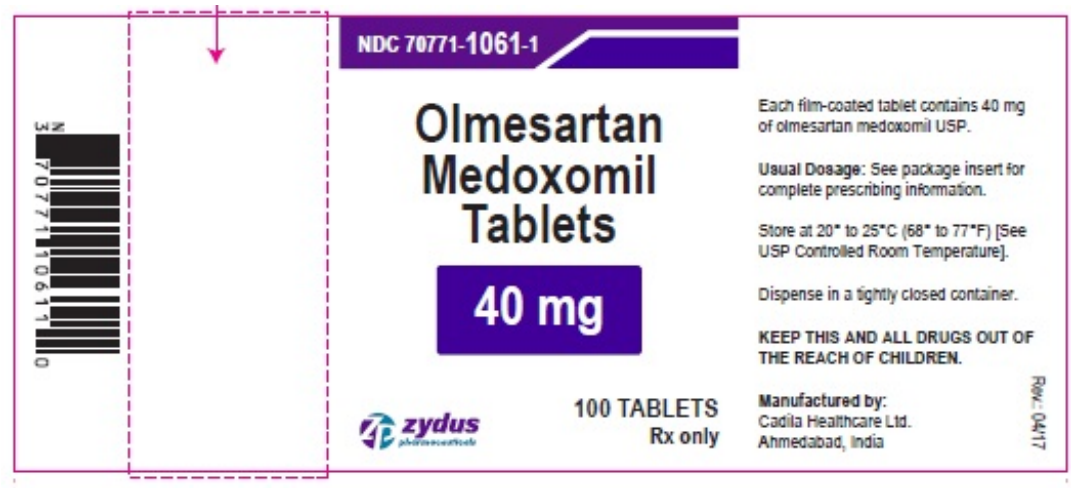


NDC 70771-1061-1

Olmesartan Medoxomil Tablets, 40 mg

Rx only

100 TABLETS



OLMESARTAN MEDOXOMIL

olmesartan medoxomil tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1059
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OLMESARTAN MEDOXOMIL (UNII: 6M97XTV3HD) (OLMESARTAN - UNII:8W1IQP3U10)	OLMESARTAN MEDOXOMIL	5 mg

Inactive Ingredients

Ingredient Name	Strength
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	9mm
Flavor		**Imprint Code**	643
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1059-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2017	
2	NDC:70771-1059-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2017	
3	NDC:70771-1059-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2017	
4	NDC:70771-1059-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2017	
5	NDC:70771-1059-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2017	
6	NDC:70771-1059-7	10 in 1 CARTON	04/24/2017	
6	NDC:70771-1059-2	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	ANDA205192	04/24/2017	

OLMESARTAN MEDOXOMIL

olmesartan medoxomil tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1060
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OLMESARTAN MEDOXOMIL (UNII: 6M97XTV3HD) (OLMESARTAN - UNII:8W1IQP3U10)	OLMESARTAN MEDOXOMIL	20 mg

Inactive Ingredients

Ingredient Name	Strength
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	9mm
Flavor		**Imprint Code**	644
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1060-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2017	
2	NDC:70771-1060-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2017	
3	NDC:70771-1060-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2017	
4	NDC:70771-	500 in 1 BOTTLE; Type 0: Not a Combination	04/24/2017	

4	1060-5	Product	04/24/2017	
5	NDC:70771-1060-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2017	
6	NDC:70771-1060-7	10 in 1 CARTON	04/24/2017	
6	NDC:70771-1060-2	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	ANDA205192	04/24/2017	

OLMESARTAN MEDOXOMIL

olmesartan medoxomil tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1061
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OLMESARTAN MEDOXOMIL (UNII: 6M97XTV3HD) (OLMESARTAN - UNII:8W1IQP3U10)	OLMESARTAN MEDOXOMIL	40 mg

Inactive Ingredients

Ingredient Name	Strength
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	OVAL (OVAL)	**Size**	15mm
Flavor		**Imprint Code**	645
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1061-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2017	
2	NDC:70771-1061-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2017	
3	NDC:70771-1061-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2017	
4	NDC:70771-1061-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2017	
5	NDC:70771-1061-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2017	
6	NDC:70771-1061-7	10 in 1 CARTON	04/24/2017	
6	NDC:70771-1061-2	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	ANDA205192	04/24/2017	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (863362789)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1059, 70771-1060, 70771-1061) , MANUFACTURE(70771-1059, 70771-1060, 70771-1061)

Revised: 10/2022 Zydus Lifesciences Limited