AMLODIPINE AND OLMESARTAN MEDOXOMIL - amlodipine and olmesartan medoxomil tablet, film coated
Zydus Lifesciences Limited

AMLODIPINE and OLMESARTAN MEDOXOMIL Tablets

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1186-3

Amlodipine and olmesartan medoxomil tablets, 5/20 mg

Rx only

30 tablets

NDC 70771-1187-3

Amlodipine and olmesartan medoxomil tablets, 10/20 mg

Rx only

30 tablets

NDC 70771-1188-3

Amlodipine and olmesartan medoxomil tablets, 5/40 mg

Rx only

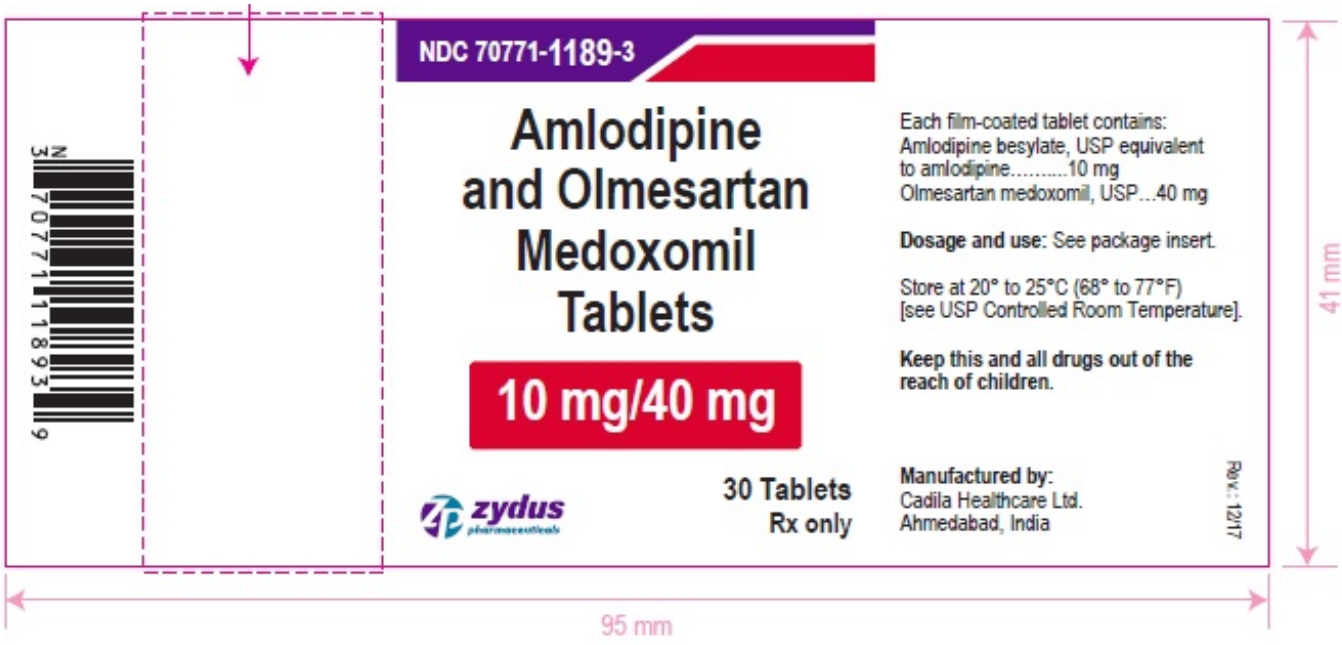
30 tablets

NDC 70771-1189-3

Amlodipine and olmesartan medoxomil tablets, 10/40 mg

Rx only

30 tablets



AMLODIPINE AND OLMESARTAN MEDOXOMIL

amlodipine and olmesartan medoxomil tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1186
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
AMLODIPINE BESYLATE (UNII: 864V2Q084H) (AMLODIPINE - UNII:1J444QC288)	AMLODIPINE	5 mg
OLMESARTAN MEDOXOMIL (UNII: 6M97XTV3HD) (OLMESARTAN - UNII:8W1IQP3U10)	OLMESARTAN MEDOXOMIL	20 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	WHITE (WHITE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	7mm
Flavor		**Imprint Code**	927
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1186-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/04/2018	
2	NDC:70771-1186-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/04/2018	
3	NDC:70771-1186-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/04/2018	
4	NDC:70771-1186-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	01/04/2018	
5	NDC:70771-1186-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/04/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207771	01/04/2018	

AMLODIPINE AND OLMESARTAN MEDOXOMIL

amlodipine and olmesartan medoxomil tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1187
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMLODIPINE BESYLATE (UNII: 864V2Q084H) (AMLODIPINE - UNII:1J444QC288)	AMLODIPINE	10 mg
OLMESARTAN MEDOXOMIL (UNII: 6M97XTV3HD) (OLMESARTAN - UNII:8W1IQP3U10)	OLMESARTAN MEDOXOMIL	20 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	ORANGE (ORANGE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	7mm
Flavor		**Imprint Code**	928
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1187-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/04/2018	
2	NDC:70771-1187-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/04/2018	
3	NDC:70771-1187-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/04/2018	
4	NDC:70771-1187-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	01/04/2018	
5	NDC:70771-1187-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/04/2018	
6	NDC:70771-1187-4	10 in 1 CARTON	01/04/2018	
6	NDC:70771-1187-2	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	ANDA207771	01/04/2018	

AMLODIPINE AND OLMESARTAN MEDOXOMIL

amlodipine and olmesartan medoxomil tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1188

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMLODIPINE BESYLATE (UNII: 864V2Q084H) (AMLODIPINE - UNII:1J444QC288)	AMLODIPINE	5 mg
OLMESARTAN MEDOXOMIL (UNII: 6M97XTV3HD) (OLMESARTAN - UNII:8W1IQP3U10)	OLMESARTAN MEDOXOMIL	40 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	YELLOW (PALE YELLOW)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	9mm
Flavor		**Imprint Code**	929
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1188-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/04/2018	
2	NDC:70771-1188-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/04/2018	
3	NDC:70771-1188-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/04/2018	
4	NDC:70771-1188-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	01/04/2018	
5	NDC:70771-1188-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/04/2018	
6	NDC:70771-1188-4	10 in 1 CARTON	01/04/2018	
6	NDC:70771-	10 in 1 BLISTER PACK; Type 0: Not a Combination		

8	1188-2	Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207771	01/04/2018	

AMLODIPINE AND OLMESARTAN MEDOXOMIL

amlodipine and olmesartan medoxomil tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1189
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMLODIPINE BESYLATE (UNII: 864V2Q084H) (AMLODIPINE - UNII:1J444QC288)	AMLODIPINE	10 mg
OLMESARTAN MEDOXOMIL (UNII: 6M97XTV3HD) (OLMESARTAN - UNII:8W1IQP3U10)	OLMESARTAN MEDOXOMIL	40 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	ORANGE (ORANGE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	9mm
Flavor		**Imprint Code**	930
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1189-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/04/2018	
2	NDC:70771-1189-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/04/2018	
3	NDC:70771-1189-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/04/2018	
4	NDC:70771-1189-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	01/04/2018	
5	NDC:70771-1189-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/04/2018	
6	NDC:70771-1189-4	10 in 1 CARTON	01/04/2018	
6	NDC:70771-1189-2	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	ANDA207771	01/04/2018	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1186, 70771-1187, 70771-1188, 70771-1189) , MANUFACTURE(70771-1186, 70771-1187, 70771-1188, 70771-1189)

Revised: 10/2022 Zydus Lifesciences Limited