ATOMOXETINE- atomoxetine capsule
Zydus Lifesciences Limited

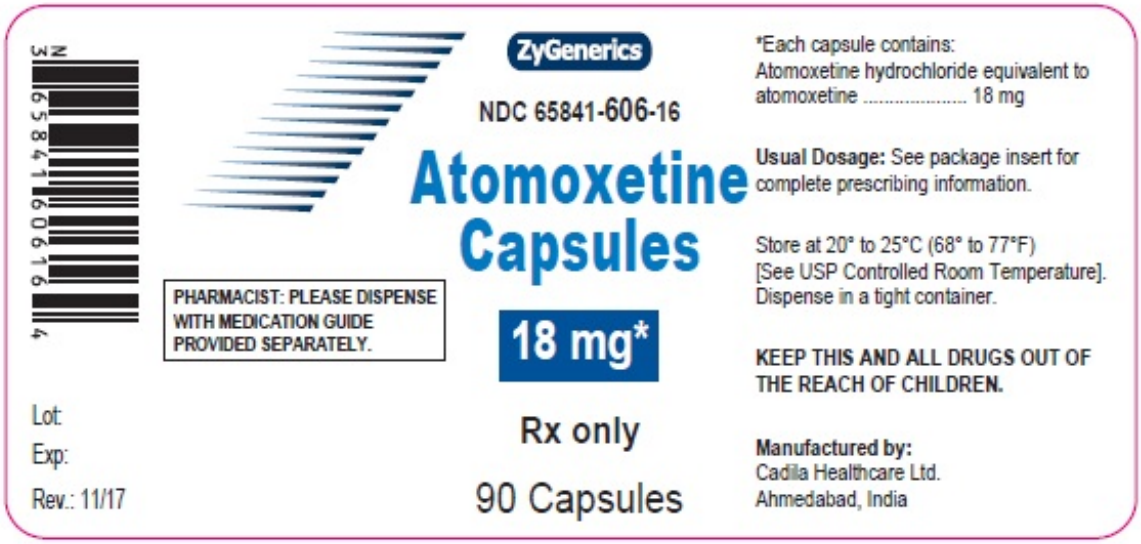
ATOMOXETINE CAPSULES

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-606-16 in bottle of 90 Capsules

Atomoxetine Capsules, 18 mg

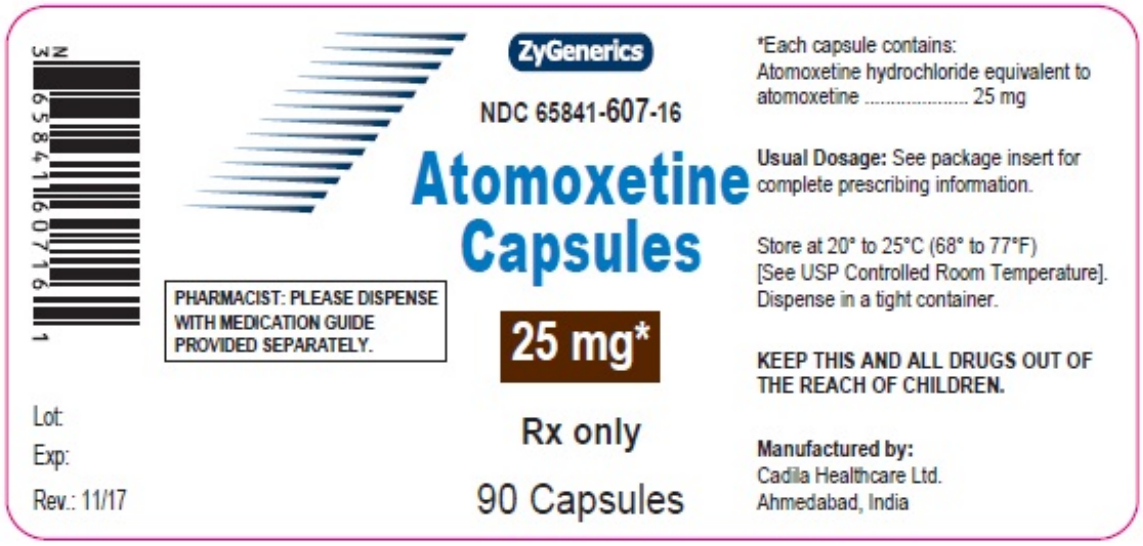
90 Capsules



NDC 65841-607-16 in bottle of 90 Capsules

Atomoxetine Capsules, 25 mg

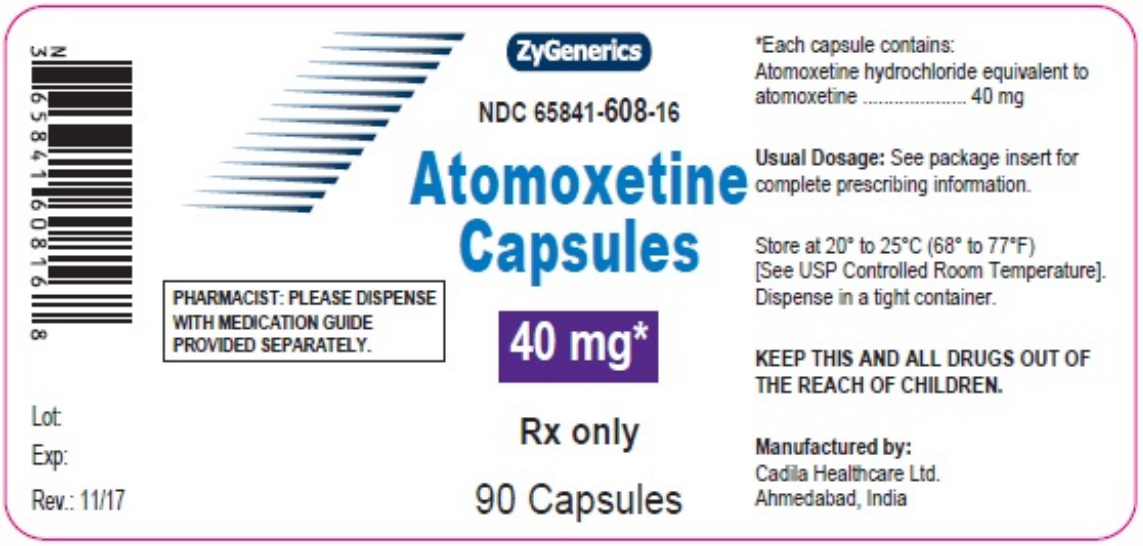
90 Capsules



NDC 65841-608-16 in bottle of 90 Capsules

Atomoxetine Capsules, 40 mg

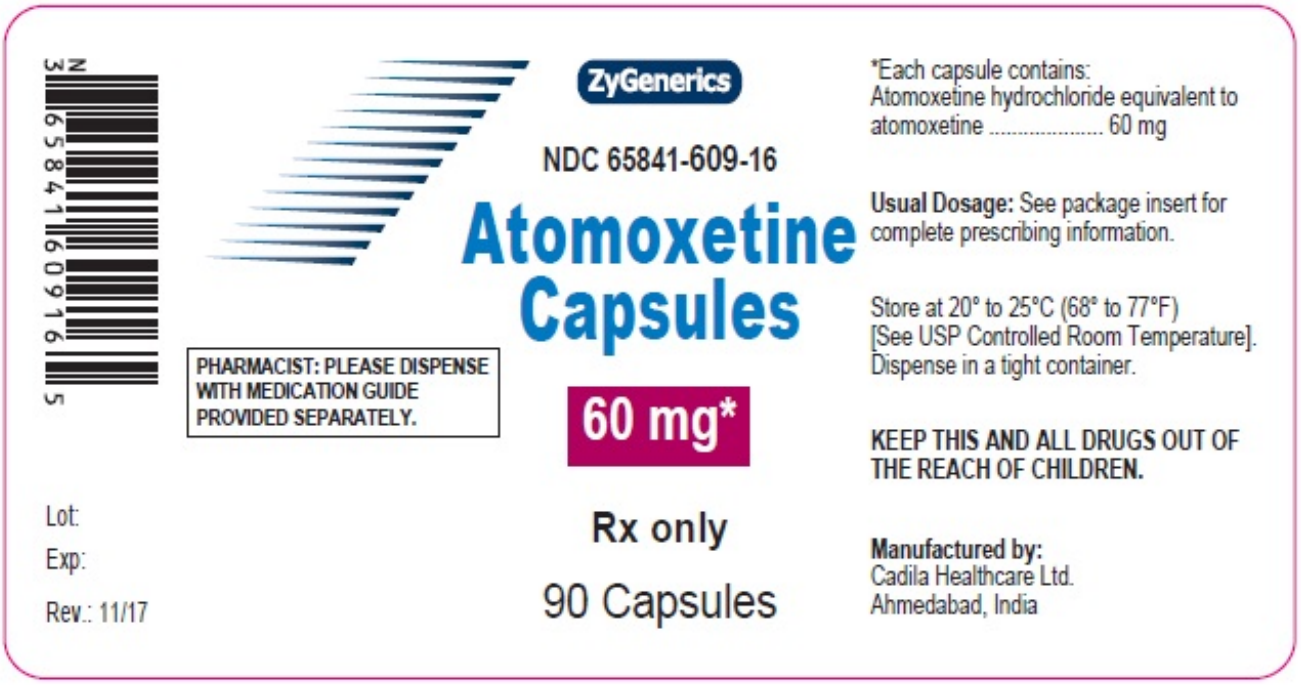
90 Capsules



NDC 65841-609-16 in bottle of 90 Capsules

Atomoxetine Capsules, 60 mg

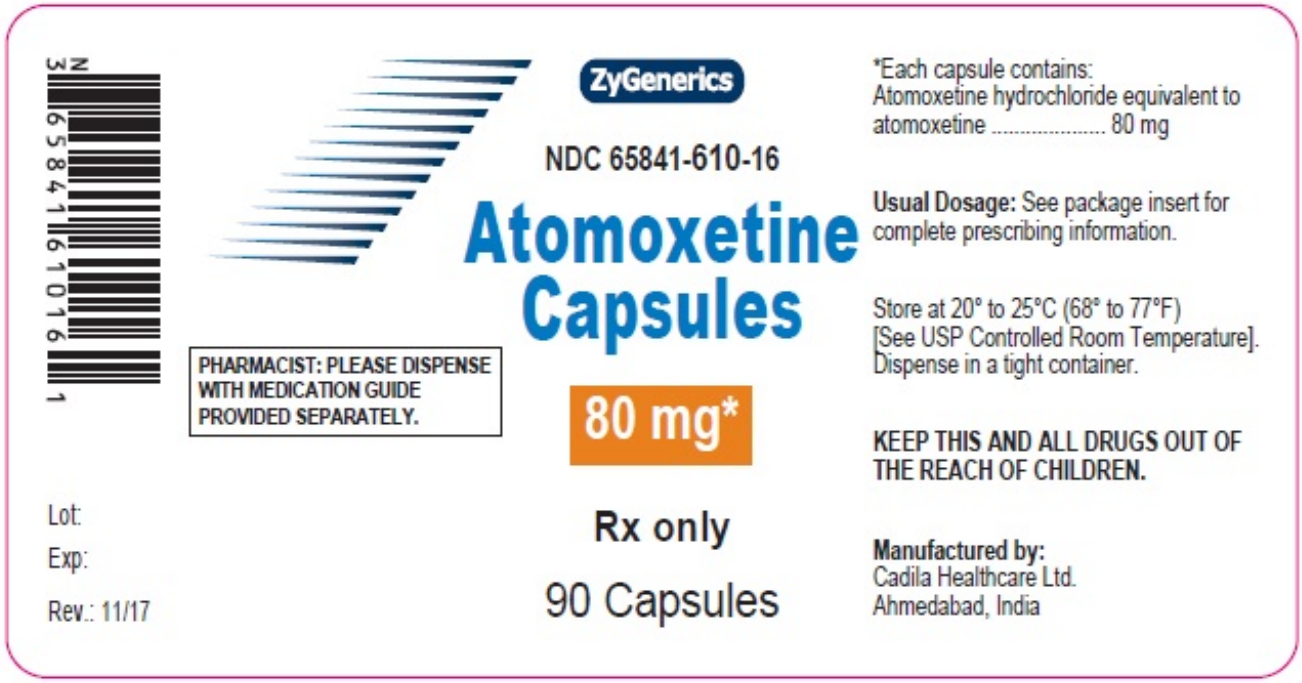
90 Capsules



NDC 65841-610-16 in bottle of 90 Capsules

Atomoxetine Capsules, 80 mg

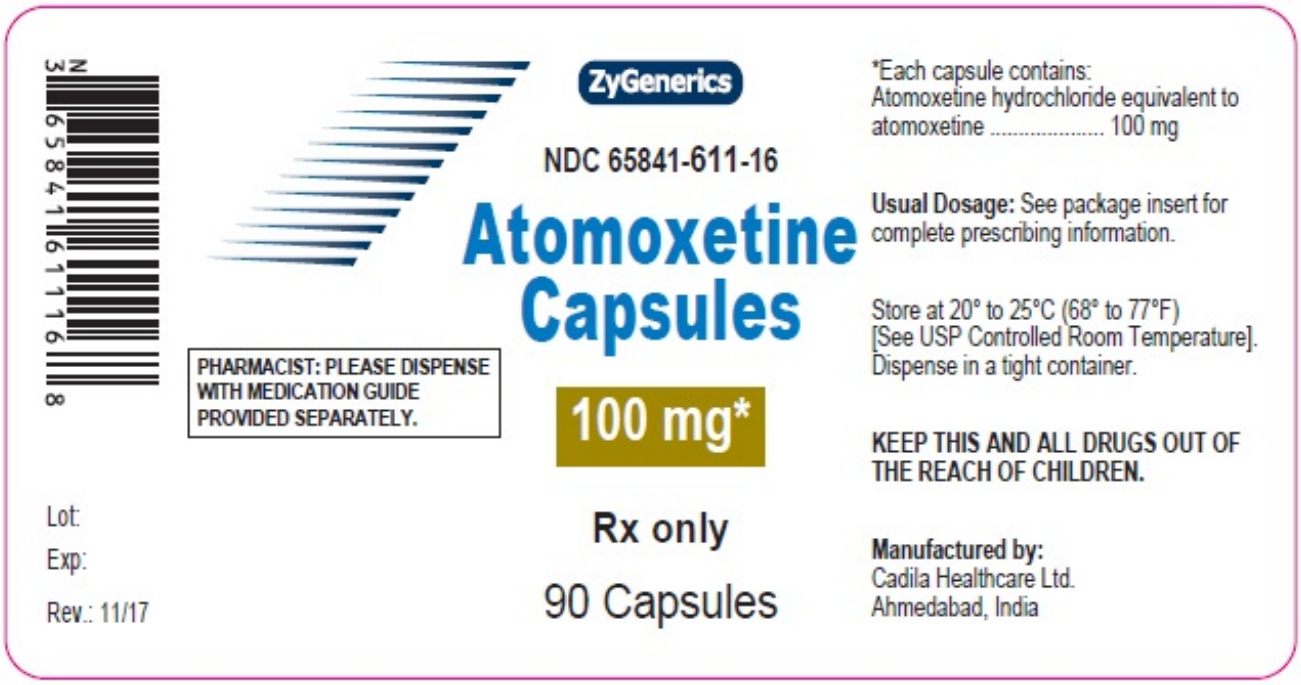
90 Capsules



NDC 65841-611-16 in bottle of 90 Capsules

Atomoxetine Capsules, 100 mg

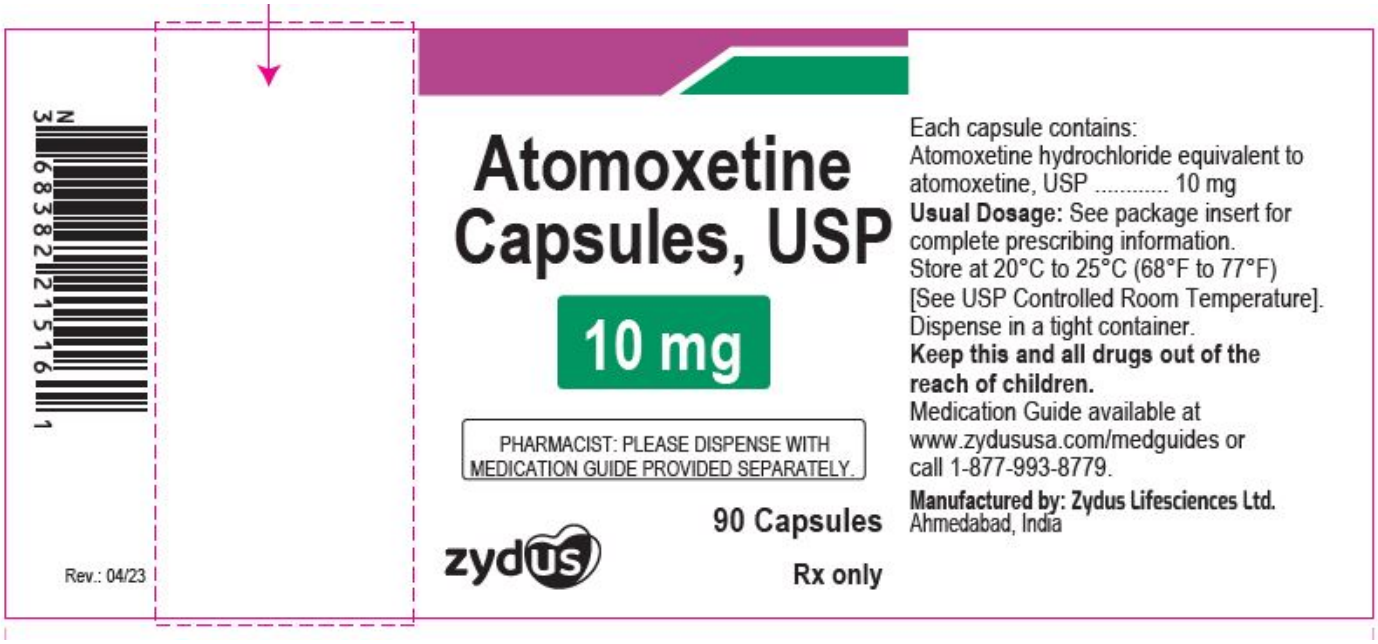
90 Capsules



NDC 65841-605-16 in bottle of 90 Capsules

Atomoxetine Capsules, 10 mg

90 Capsules



ATOMOXETINE atomoxetine capsule
Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-606
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ATOMOXETINE HYDROCHLORIDE (UNII: 57WVB6I2W0) (ATOMOXETINE - UNII:ASW034S0B8)	ATOMOXETINE	18 mg

Inactive Ingredients

Ingredient Name	Strength
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	YELLOW (GOLDEN) , WHITE (WHITE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	14mm
Flavor		**Imprint Code**	ZA;68
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-606-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/06/2017	
2	NDC:65841-606-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	12/06/2017	
3	NDC:65841-606-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/06/2017	
4	NDC:65841-606-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/06/2017	
5	NDC:65841-606-02	2000 in 1 BOTTLE; Type 0: Not a Combination Product	12/06/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

ANDA	ANDA079017	12/06/2017	

ATOMOXETINE

atomoxetine capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-607
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ATOMOXETINE HYDROCHLORIDE (UNII: 57WVB6I2W0) (ATOMOXETINE - UNII:ASW034S0B8)	ATOMOXETINE	25 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BLUE (OPAQUE BLUE) , WHITE (OPAQUE WHITE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	18mm
Flavor		**Imprint Code**	ZA69;25mg
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-607-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/06/2017	
2	NDC:65841-607-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	12/06/2017	
3	NDC:65841-607-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/06/2017	
4	NDC:65841-	1000 in 1 BOTTLE; Type 0: Not a Combination	12/06/2017	

4	607-10	Product	12/06/2017	
5	NDC:65841-607-02	2000 in 1 BOTTLE; Type 0: Not a Combination Product	12/06/2017	
6	NDC:65841-607-77	10 in 1 CARTON	12/06/2017	
6	NDC:65841-607-30	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	ANDA079017	12/06/2017	

ATOMOXETINE

atomoxetine capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-608
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ATOMOXETINE HYDROCHLORIDE (UNII: 57WVB6I2W0) (ATOMOXETINE - UNII:ASW034S0B8)	ATOMOXETINE	40 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
GELATIN (UNII: 2G86QN327L)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SHELLAC (UNII: 46N107B71O)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	

Product Characteristics

Color	BLUE (OPAQUE BLUE) , BLUE (OPAQUE BLUE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	18mm
Flavor		**Imprint Code**	ZA70;40mg
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-608-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/06/2017	
2	NDC:65841-608-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	12/06/2017	
3	NDC:65841-608-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/06/2017	
4	NDC:65841-608-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/06/2017	
5	NDC:65841-608-02	2000 in 1 BOTTLE; Type 0: Not a Combination Product	12/06/2017	
6	NDC:65841-608-77	10 in 1 CARTON	12/06/2017	
6	NDC:65841-608-30	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	ANDA079017	12/06/2017	

ATOMOXETINE

atomoxetine capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-609
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ATOMOXETINE HYDROCHLORIDE (UNII: 57WVB6I2W0) (ATOMOXETINE - UNII:ASW034S0B8)	ATOMOXETINE	60 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BLUE (OPAQUE BLUE) , YELLOW (GOLDEN)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	19mm
Flavor		**Imprint Code**	ZA71;60mg
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-609-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/06/2017	
2	NDC:65841-609-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	12/06/2017	
3	NDC:65841-609-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/06/2017	
4	NDC:65841-609-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/06/2017	
5	NDC:65841-609-02	2000 in 1 BOTTLE; Type 0: Not a Combination Product	12/06/2017	
6	NDC:65841-609-77	10 in 1 CARTON	12/06/2017	
6	NDC:65841-609-30	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	ANDA079017	12/06/2017	

ATOMOXETINE

atomoxetine capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-610
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of	Strength

Ingredient Name	Strength	Strength
ATOMOXETINE HYDROCHLORIDE (UNII: 57WVB6I2W0) (ATOMOXETINE - UNII:ASW034S0B8)	ATOMOXETINE	80 mg

Inactive Ingredients

Ingredient Name	Strength
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BROWN (OPAQUE BROWN) , WHITE (WHITE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	19mm
Flavor		**Imprint Code**	ZA72;80mg
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-610-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/06/2017	
2	NDC:65841-610-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	12/06/2017	
3	NDC:65841-610-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/06/2017	
4	NDC:65841-610-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/06/2017	
5	NDC:65841-610-02	2000 in 1 BOTTLE; Type 0: Not a Combination Product	12/06/2017	
6	NDC:65841-610-77	10 in 1 CARTON	12/06/2017	
6	NDC:65841-610-30	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	ANDA079017	12/06/2017	

ATOMOXETINE

atomoxetine capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-611
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ATOMOXETINE HYDROCHLORIDE (UNII: 57WVB6I2W0) (ATOMOXETINE - UNII:ASW034S0B8)	ATOMOXETINE	100 mg

Inactive Ingredients

Ingredient Name	Strength
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
GELATIN (UNII: 2G86QN327L)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	BROWN (OPAQUE BROWN) , BROWN (OPAQUE BROWN)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	21mm
Flavor		**Imprint Code**	ZA73;100mg
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-611-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	12/06/2017	
2	NDC:65841-611-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/06/2017	
3	NDC:65841-611-02	2000 in 1 BOTTLE; Type 0: Not a Combination Product	12/06/2017	
4	NDC:65841-611-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/06/2017	
5	NDC:65841-611-	90 in 1 BOTTLE; Type 0: Not a Combination	12/06/2017	

3	16	Product	12/06/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079017	12/06/2017	

ATOMOXETINE

atomoxetine capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-605
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ATOMOXETINE HYDROCHLORIDE (UNII: 57WVB6I2W0) (ATOMOXETINE - UNII:ASW034S0B8)	ATOMOXETINE	10 mg

Inactive Ingredients

Ingredient Name	Strength
AMMONIA (UNII: 5138Q19F1X)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	WHITE (OPAQUE WHITE) , WHITE (OPAQUE WHITE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	11mm
Flavor		**Imprint Code**	ZA;67;10mg
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-605-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/05/2023	
2	NDC:65841-605-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/05/2023	
3	NDC:65841-605-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	04/05/2023	
4	NDC:65841-605-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	04/05/2023	
5	NDC:65841-605-02	2000 in 1 BOTTLE; Type 0: Not a Combination Product	04/05/2023	
6	NDC:65841-605-77	10 in 1 CARTON	04/05/2023	
6	NDC:65841-605-30	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	ANDA079017	04/05/2023	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(65841-605, 65841-606, 65841-607, 65841-608, 65841-609, 65841-610, 65841-611) , MANUFACTURE(65841-605, 65841-606, 65841-607, 65841-608, 65841-609, 65841-610, 65841-611)

Revised: 12/2023 Zydus Lifesciences Limited