

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

ZyGenerics
NDC 65841-606-16

**Atomoxetine
Capsules**

18 mg*

Rx only

90 Capsules

PHARMACIST: PLEASE DISPENSE
WITH MEDICATION GUIDE
PROVIDED SEPARATELY.

*Each capsule contains:
Atomoxetine hydrochloride equivalent to
atomoxetine 18 mg

Usual Dosage: See package insert for
complete prescribing information.

Store at 20° to 25°C (68° to 77°F)
[See USP Controlled Room Temperature].
Dispense in a tight container.

**KEEP THIS AND ALL DRUGS OUT OF
THE REACH OF CHILDREN.**

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Lot:
Exp:
Rev: 11/17

NDC 65841-607-16 in bottle of 90 Capsules

Atomoxetine Capsules, 25 mg

90 Capsules

ZyGenerics
NDC 65841-607-16

Atomoxetine Capsules

25 mg*

Rx only
90 Capsules

*Each capsule contains:
Atomoxetine hydrochloride equivalent to
atomoxetine 25 mg

Usual Dosage: See package insert for
complete prescribing information.

Store at 20° to 25°C (68° to 77°F)
[See USP Controlled Room Temperature].
Dispense in a tight container.

**KEEP THIS AND ALL DRUGS OUT OF
THE REACH OF CHILDREN.**

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

PHARMACIST: PLEASE DISPENSE
WITH MEDICATION GUIDE
PROVIDED SEPARATELY.

Lot:
Exp:
Rev.: 11/17

NDC 65841-608-16 in bottle of 90 Capsules
Atomoxetine Capsules, 40 mg
90 Capsules

ZyGenerics
NDC 65841-608-16

Atomoxetine Capsules

40 mg*

Rx only
90 Capsules

*Each capsule contains:
Atomoxetine hydrochloride equivalent to
atomoxetine 40 mg

Usual Dosage: See package insert for
complete prescribing information.

Store at 20° to 25°C (68° to 77°F)
[See USP Controlled Room Temperature].
Dispense in a tight container.

**KEEP THIS AND ALL DRUGS OUT OF
THE REACH OF CHILDREN.**

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

PHARMACIST: PLEASE DISPENSE
WITH MEDICATION GUIDE
PROVIDED SEPARATELY.

Lot:
Exp:
Rev.: 11/17

NDC 65841-609-16 in bottle of 90 Capsules
Atomoxetine Capsules, 60 mg
90 Capsules

3N
65841609165

ZyGenerics

NDC 65841-609-16

Atomoxetine Capsules

60 mg*

Rx only

90 Capsules

PHARMACIST: PLEASE DISPENSE WITH MEDICATION GUIDE PROVIDED SEPARATELY.

Lot:
Exp:
Rev.: 11/17

*Each capsule contains:
Atomoxetine hydrochloride equivalent to atomoxetine 60 mg

Usual Dosage: See package insert for complete prescribing information.

Store at 20° to 25°C (68° to 77°F)
[See USP Controlled Room Temperature].
Dispense in a tight container.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

NDC 65841-610-16 in bottle of 90 Capsules

Atomoxetine Capsules, 80 mg

90 Capsules

3N
65841610161

ZyGenerics

NDC 65841-610-16

Atomoxetine Capsules

80 mg*

Rx only

90 Capsules

PHARMACIST: PLEASE DISPENSE WITH MEDICATION GUIDE PROVIDED SEPARATELY.

Lot:
Exp:
Rev.: 11/17

*Each capsule contains:
Atomoxetine hydrochloride equivalent to atomoxetine 80 mg

Usual Dosage: See package insert for complete prescribing information.

Store at 20° to 25°C (68° to 77°F)
[See USP Controlled Room Temperature].
Dispense in a tight container.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

NDC 65841-611-16 in bottle of 90 Capsules

Atomoxetine Capsules, 100 mg

90 Capsules

3
N
6
5
8
4
1
6
1
1
1
6
8

ZyGenerics

NDC 65841-611-16

Atomoxetine Capsules

100 mg*

Rx only

90 Capsules

PHARMACIST: PLEASE DISPENSE WITH MEDICATION GUIDE PROVIDED SEPARATELY.

*Each capsule contains:
Atomoxetine hydrochloride equivalent to atomoxetine 100 mg

Usual Dosage: See package insert for complete prescribing information.

Store at 20° to 25°C (68° to 77°F)
[See USP Controlled Room Temperature].
Dispense in a tight container.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Lot:
Exp:
Rev.: 11/17

NDC 65841-605-16 in bottle of 90 Capsules

Atomoxetine Capsules, 10 mg

90 Capsules

3
N
6
8
3
8
2
2
1
5
1
6
1

Atomoxetine Capsules, USP

10 mg

90 Capsules

Rx only

PHARMACIST: PLEASE DISPENSE WITH MEDICATION GUIDE PROVIDED SEPARATELY.

Each capsule contains:
Atomoxetine hydrochloride equivalent to atomoxetine, USP 10 mg

Usual Dosage: See package insert for complete prescribing information.

Store at 20°C to 25°C (68°F to 77°F)
[See USP Controlled Room Temperature].
Dispense in a tight container.

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.

Manufactured by: Zydus Lifesciences Ltd.
Ahmedabad, India

Rev.: 04/23

zydus

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)	
FERROSFERRIC 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)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B710)	
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)	
FERROSO FERRIC 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)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
POTASSIUM HYDROXIDE (UNII: WZ H3C48M4T)	
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)	
FERROSFERRIC 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)	
FERROSFERRIC 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	

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)	
FERROSFERRIC 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