OXYBUTYNIN- oxybutynin tablet, film coated, extended release
Cadila Healthcare Limited

OXYBUTYNIN CHLORIDE EXTENDED-RELEASE TABLETS

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Oxybutynin chloride extended-release tablets USP, 5 mg

NDC 70771-1086-3

30 tablets

Rx only

Oxybutynin chloride extended-release tablets USP, 10 mg

NDC 70771-1087-3

30 tablets

Rx only

Oxybutynin chloride extended-release tablets USP, 15 mg

NDC 70771-1088-3

30 tablets

Rx only

OXYBUTYNIN

oxybutynin tablet, film coated, extended release

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1086
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
OXYBUTYNIN CHLORIDE (UNII: L9F3D9RENQ) (OXYBUTYNIN - UNII:K9P6MC7092)	OXYBUTYNIN CHLORIDE	5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ALGINIC ACID (UNII: 8C3Z4148WZ)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID (UNII: 1CS02G8656)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics			
Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	7mm
Flavor		**Imprint Code**	255
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70771-1086-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2017	
2	NDC:70771-1086-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2017	
3	NDC:70771-1086-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2017	
4	NDC:70771-1086-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2017	
5	NDC:70771-1086-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2017	
6	NDC:70771-1086-4	10 in 1 CARTON	08/10/2017	
6	NDC:70771-1086-2	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	ANDA202332	08/10/2017	

OXYBUTYNIN

oxybutynin tablet, film coated, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1087
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYBUTYNIN CHLORIDE (UNII: L9F3D9RENQ) (OXYBUTYNIN - UNII:K9P6MC7092)	OXYBUTYNIN CHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
ALGINIC ACID (UNII: 8C3Z4148WZ)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID (UNII: 1CS02G8656)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	7mm
Flavor		**Imprint Code**	256
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1087-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2017	
2	NDC:70771-1087-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2017	
3	NDC:70771-1087-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2017	
4	NDC:70771-1087-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2017	
5	NDC:70771-1087-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2017	
6	NDC:70771-1087-4	10 in 1 CARTON	08/10/2017	
6	NDC:70771-1087-2	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	ANDA202332	08/10/2017	

OXYBUTYNIN

oxybutynin tablet, film coated, extended release

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1088
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
OXYBUTYNIN CHLORIDE (UNII: L9F3D9RENQ) (OXYBUTYNIN - UNII:K9P6MC7092)	OXYBUTYNIN CHLORIDE	15 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ALGINIC ACID (UNII: 8C3Z4148WZ)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID (UNII: 1CS02G8656)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics			
Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	7mm
Flavor		**Imprint Code**	257
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70771-1088-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2017	
2	NDC:70771-1088-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2017	
3	NDC:70771-1088-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2017	
4	NDC:70771-1088-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2017	
5	NDC:70771-1088-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2017	
6	NDC:70771-1088-4	10 in 1 CARTON	08/10/2017	
6	NDC:70771-1088-2	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	ANDA202332	08/10/2017	

Labeler - Cadila Healthcare Limited (918596198)

Registrant - Cadila Healthcare Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Cadila Healthcare Limited		918596198	ANALYSIS(70771-1086, 70771-1087, 70771-1088) , MANUFACTURE(70771-1086, 70771-1087, 70771-1088)

Revised: 9/2020 Cadila Healthcare Limited