

**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

NDC 70771-1086-3

**Oxybutynin Chloride  
Extended-Release  
Tablets**

**5 mg**

Swallow tablets whole.  
Do not chew, divide or crush tablets.

**zydus**  
pharmaceuticals

**30 TABLETS**  
Rx only

Each film-coated extended-release tablet contains 5 mg of oxybutynin chloride, USP.

**Usual Dosage:** Once daily. See package insert for complete prescribing information.

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

Protect from moisture and humidity.

Dispense in a tight container.

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

Manufactured by:  
Cadila Healthcare Ltd.  
Ahmedabad, India

RAU: 09/19

N  
317077111086313

Oxybutynin chloride extended-release tablets USP, 10 mg

NDC 70771-1087-3

30 tablets

Rx only



NDC 70771-1087-3

## Oxybutynin Chloride Extended-Release Tablets

10 mg



Swallow tablets whole.  
Do not chew, divide or crush tablets.

Each film-coated extended-release tablet contains 10 mg of oxybutynin chloride, USP.

**Usual Dosage:** Once daily. See package insert for complete prescribing information.

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

Protect from moisture and humidity.

Dispense in a tight container.

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

Manufactured by:  
Cadila Healthcare Ltd.  
Ahmedabad, India

Rev: 09/19



30 TABLETS

Rx only

Oxybutynin chloride extended-release tablets USP, 15 mg  
 NDC 70771-1088-3  
 30 tablets  
 Rx only



NDC 70771-1088-3

## Oxybutynin Chloride Extended-Release Tablets

15 mg



Swallow tablets whole.  
Do not chew, divide or crush tablets.

Each film-coated extended-release tablet contains 15 mg of oxybutynin chloride, USP.

**Usual Dosage:** Once daily. See package insert for complete prescribing information.

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

Protect from moisture and humidity.

Dispense in a tight container.

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

Manufactured by:  
Cadila Healthcare Ltd.  
Ahmedabad, India

Rev: 09/19



30 TABLETS

Rx only

## OXYBUTYNIN

oxybutynin tablet, film coated, extended release

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1086
<b>Route of Administration</b>	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**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1087
<b>Route of Administration</b>	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

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

### 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

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1088
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
OXYBUTYNIN CHLORIDE (UNII: L9F3D9RENQ) (OXYBUTYNIN - UNII:K9P6MC7092)	OXYBUTYNIN CHLORIDE	15 mg

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
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

<b>Color</b>	WHITE (WHITE TO OFF-WHITE)	<b>Score</b>	no score
<b>Shape</b>	ROUND (ROUND)	<b>Size</b>	7mm
<b>Flavor</b>		<b>Imprint Code</b>	257
<b>Contains</b>			

### 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

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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