

OXYBUTYNIN- oxybutynin tablet, film coated, extended release
Zydus Lifesciences Limited

OXYBUTYNIN CHLORIDE EXTENDED-RELEASE TABLETS

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Oxybutynin chloride extended-release tablets USP, 5 mg

NDC 70771-1086-1

100 tablets

Rx only

3 683821255011 3

**Oxybutynin Chloride
Extended-Release
Tablets, USP**

5 mg

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

zydus

**100 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°C to 25°C (68°F 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: **Zydus Lifesciences Ltd.**
Ahmedabad, India

GUJDRUGS/G/25/1486
XXXXXXXX
Rev.: 07/24

Oxybutynin chloride extended-release tablets USP, 10 mg

NDC 70771-1087-1

100 tablets

Rx only

3 N
683821256010

GUJDRUGS/G/25/1486
XXXXXXXX
Rev.: 07/24

Oxybutynin Chloride Extended-Release Tablets, USP

10 mg

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

zydus

100 Tablets
Rx only

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°C to 25°C (68°F 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: Zydus Lifesciences Ltd.
Ahmedabad, India

Oxybutynin chloride extended-release tablets USP, 15 mg
NDC 70771-1088-1
100 tablets
Rx only

3 N
683821257017

GUJDRUGS/G/25/1486
XXXXXXXX
Rev.: 07/24

Oxybutynin Chloride Extended-Release Tablets, USP

15 mg

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

zydus

100 Tablets
Rx only

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°C to 25°C (68°F 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: Zydus Lifesciences Ltd.
Ahmedabad, India

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 - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

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

Revised: 12/2024

Zydus Lifesciences Limited