PROPRANOLOL HYDROCHLORIDE - propranolol hydrochloride capsule, extended release
Zydus Lifesciences Limited

Propranolol Hydrochloride Extended-release Capsules, USP

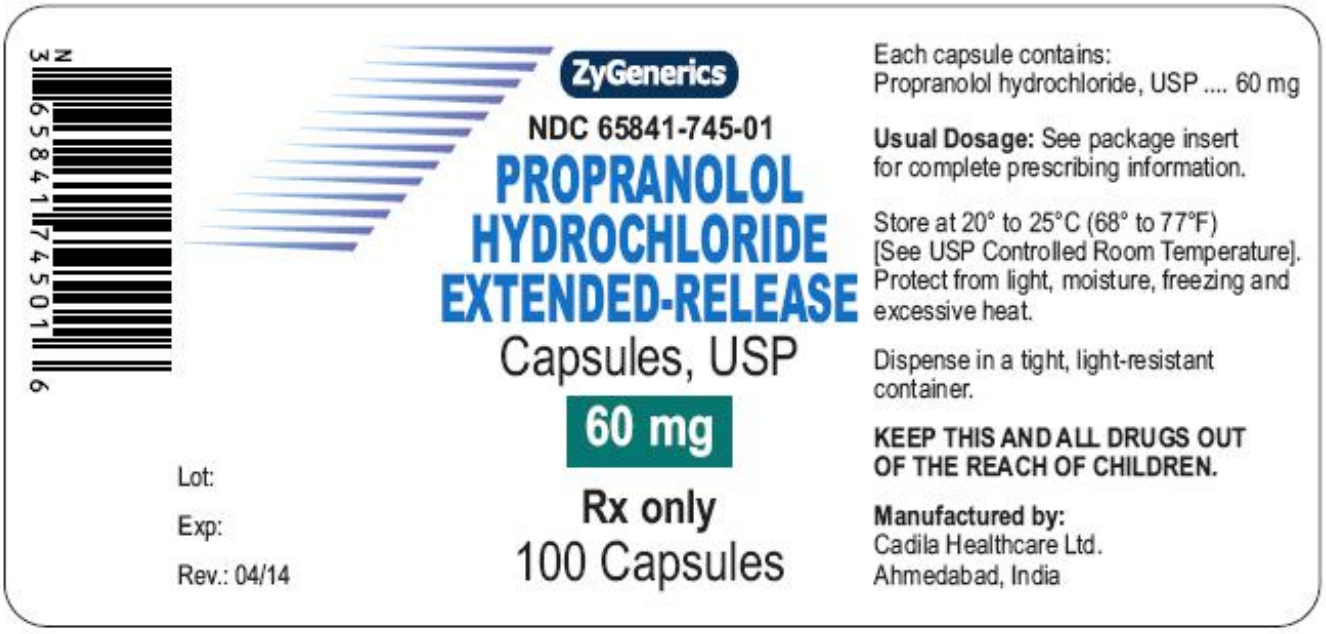
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-745-01 in bottle of 100 Capsules

Propranolol Hydrochloride Extended-release Capsules USP, 60 mg

Rx only

100 CAPSULES

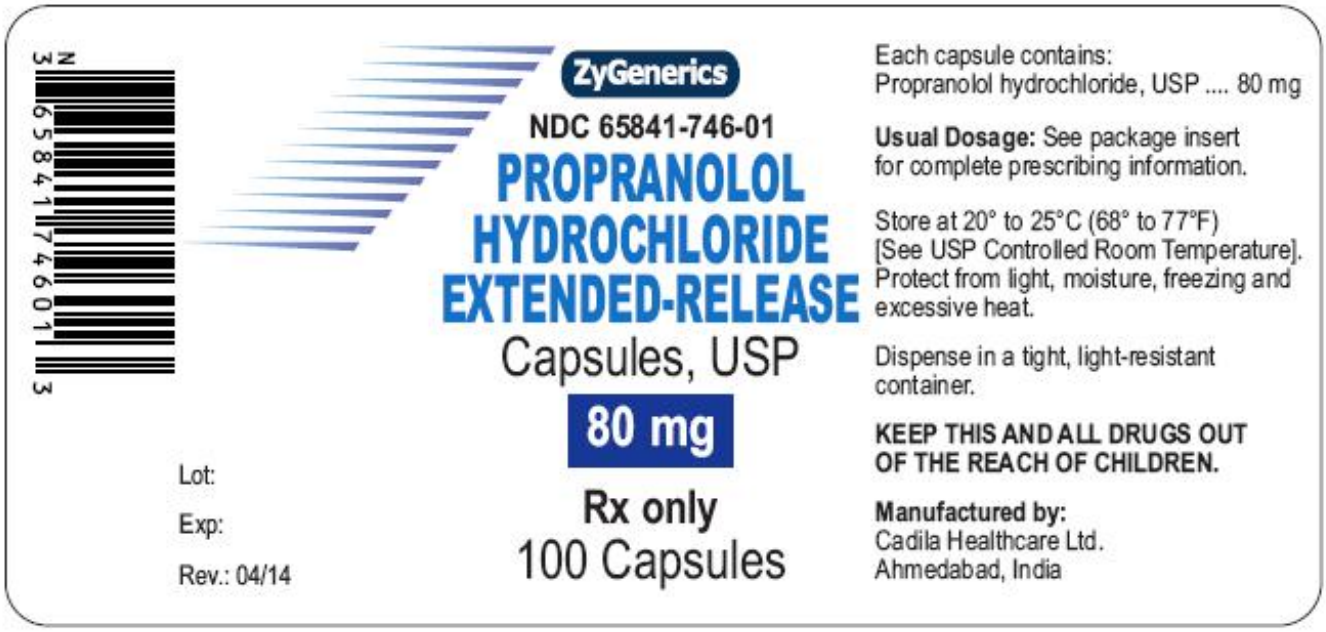


NDC 65841-746-01 in bottle of 100 Capsules

Propranolol Hydrochloride Extended-release Capsules USP, 80 mg

Rx only

100 CAPSULES



NDC 65841-747-01 in bottle of 100 Capsules

Propranolol Hydrochloride Extended-release Capsules USP, 120 mg

Rx only

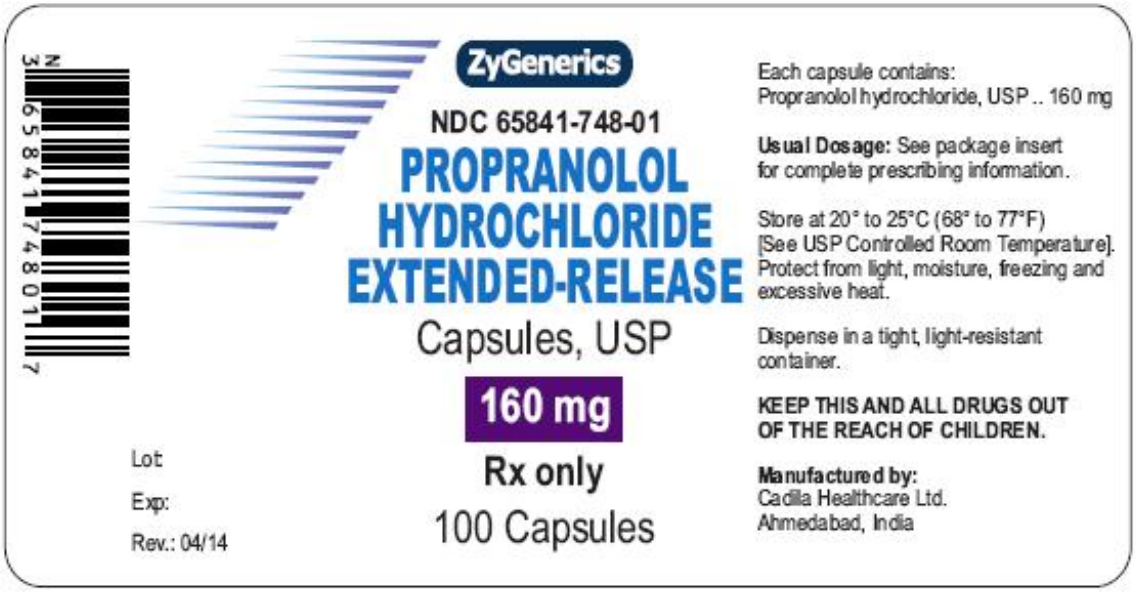
100 CAPSULES

NDC 65841-748-01 in bottle of 100 Capsules

Propranolol Hydrochloride Extended-release Capsules USP, 160 mg

Rx only

100 CAPSULES



PROPRANOLOL HYDROCHLORIDE

propranolol hydrochloride capsule, extended release

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-745
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PROPRANOLOL HYDROCHLORIDE (UNII: F8A3652H1V) (PROPRANOLOL - UNII:9Y8NXQ24VQ)	PROPRANOLOL HYDROCHLORIDE	60 mg

Inactive Ingredients	
Ingredient Name	**Strength**
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
ETHYLCELLULOSES (UNII: 7Z8S9VYZ4B)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

Product Characteristics			
Color	WHITE (WHITE) , BLUE (LIGHT BLUE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	16mm

Flavor		**Imprint Code**	ZA;57;60;mg
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-745-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2014	
2	NDC:65841-745-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2014	
3	NDC:65841-745-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2014	
4	NDC:65841-745-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2014	
5	NDC:65841-745-77	100 in 1 CARTON	04/15/2014	
5	NDC:65841-745-30	1 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	ANDA090321	04/15/2014	

PROPRANOLOL HYDROCHLORIDE

propranolol hydrochloride capsule, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-746
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PROPRANOLOL HYDROCHLORIDE (UNII: F8A3652H1V) (PROPRANOLOL - UNII:9Y8NXQ24VQ)	PROPRANOLOL HYDROCHLORIDE	80 mg

Inactive Ingredients

Ingredient Name	Strength
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
ETHYLCELLULOSES (UNII: 7Z8S9VYZ4B)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

Product Characteristics

Color	BLUE (LIGHT BLUE) , BLUE (LIGHT BLUE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	16mm
Flavor		**Imprint Code**	ZA;58;80;mg
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-746-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2014	
2	NDC:65841-746-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2014	
3	NDC:65841-746-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2014	
4	NDC:65841-746-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2014	
5	NDC:65841-746-77	100 in 1 CARTON	04/15/2014	
5	NDC:65841-746-30	1 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	ANDA090321	04/15/2014	

PROPRANOLOL HYDROCHLORIDE

propranolol hydrochloride capsule, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-747
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PROPRANOLOL HYDROCHLORIDE (UNII: F8A3652H1V) (PROPRANOLOL - UNII:9Y8NXQ24VQ)	PROPRANOLOL HYDROCHLORIDE	120 mg

Inactive Ingredients

Ingredient Name	Strength
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
ETHYLCELLULOSES (UNII: 7Z8S9VYZ4B)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

Product Characteristics

Color	BLUE (DARK BLUE) , BLUE (LIGHT BLUE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	18mm
Flavor		**Imprint Code**	ZA;59;120;mg
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-747-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2014	
2	NDC:65841-747-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2014	
3	NDC:65841-747-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2014	
4	NDC:65841-747-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2014	
5	NDC:65841-747-77	100 in 1 CARTON	04/15/2014	
5	NDC:65841-747-30	1 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	ANDA090321	04/15/2014	

PROPRANOLOL HYDROCHLORIDE

propranolol hydrochloride capsule, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-748
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PROPRANOLOL HYDROCHLORIDE (UNII: F8A3652H1V) (PROPRANOLOL - UNII:9Y8NXQ24VQ)	PROPRANOLOL HYDROCHLORIDE	160 mg

Inactive Ingredients

Ingredient Name	Strength
ETHYLCELLULOSES (UNII: 7Z8S9VYZ4B)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

Product Characteristics

Color	BLUE (DARK BLUE) , BLUE (DARK BLUE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	19mm
Flavor		**Imprint Code**	ZA;60;160;mg
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-748-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2014	
2	NDC:65841-748-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2014	
3	NDC:65841-748-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2014	
4	NDC:65841-748-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2014	
5	NDC:65841-748-77	100 in 1 CARTON	04/15/2014	
5	NDC:65841-748-30	1 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	ANDA090321	04/15/2014	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(65841-745, 65841-746, 65841-747, 65841-748) , MANUFACTURE(65841-745, 65841-746, 65841-747, 65841-748)

Revised: 10/2022

Zydus Lifesciences Limited