LABETALOL HYDROCHLORIDE - labetalol hydrochloride tablet, film coated
Zydus Lifesciences Limited

Labetalol Hydrochloride Tablets, USP
Rx only

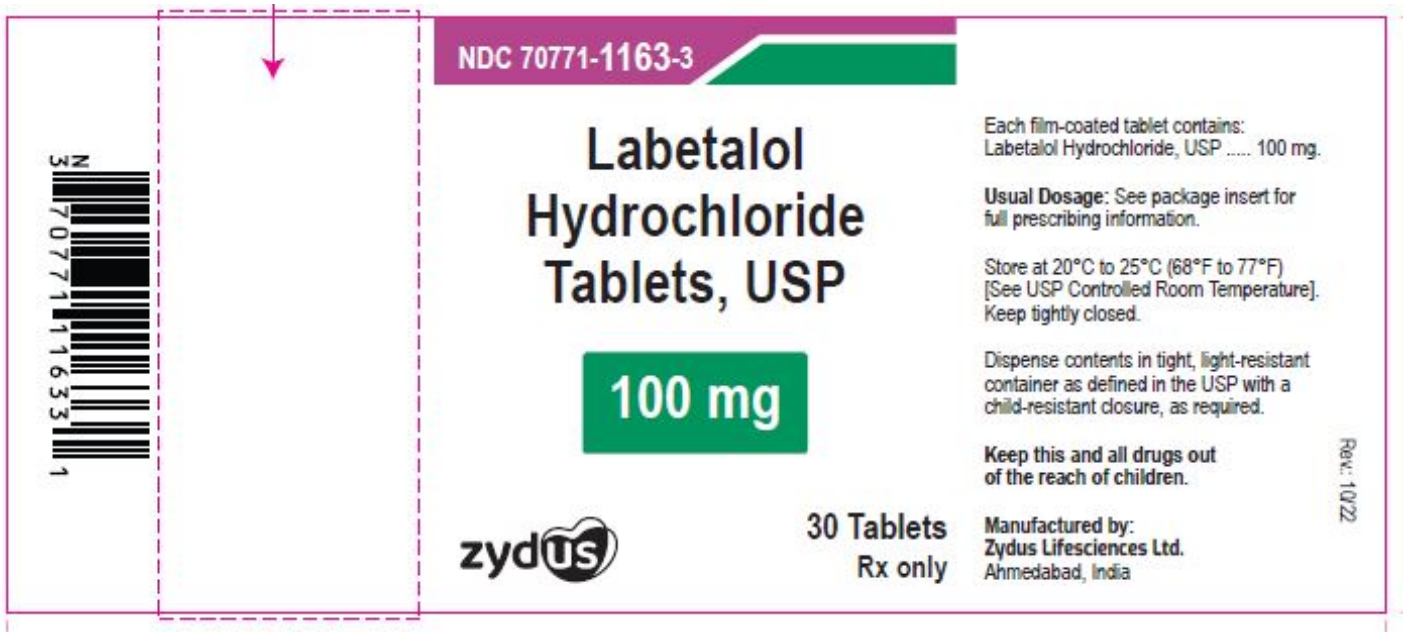
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1163-3

Labetalol hydrochloride tablets, 100 mg

Rx only

30 tablets

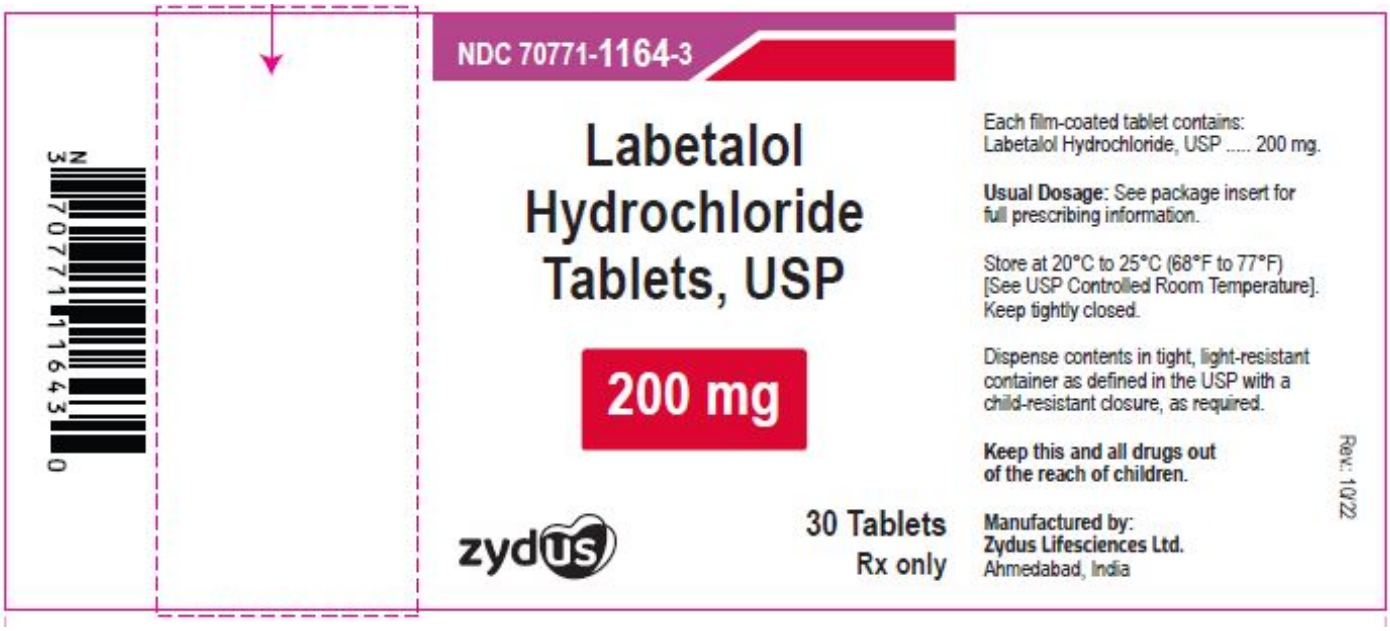


NDC 70771-1164-3

Labetalol hydrochloride tablets, 200 mg

Rx only

30 tablets

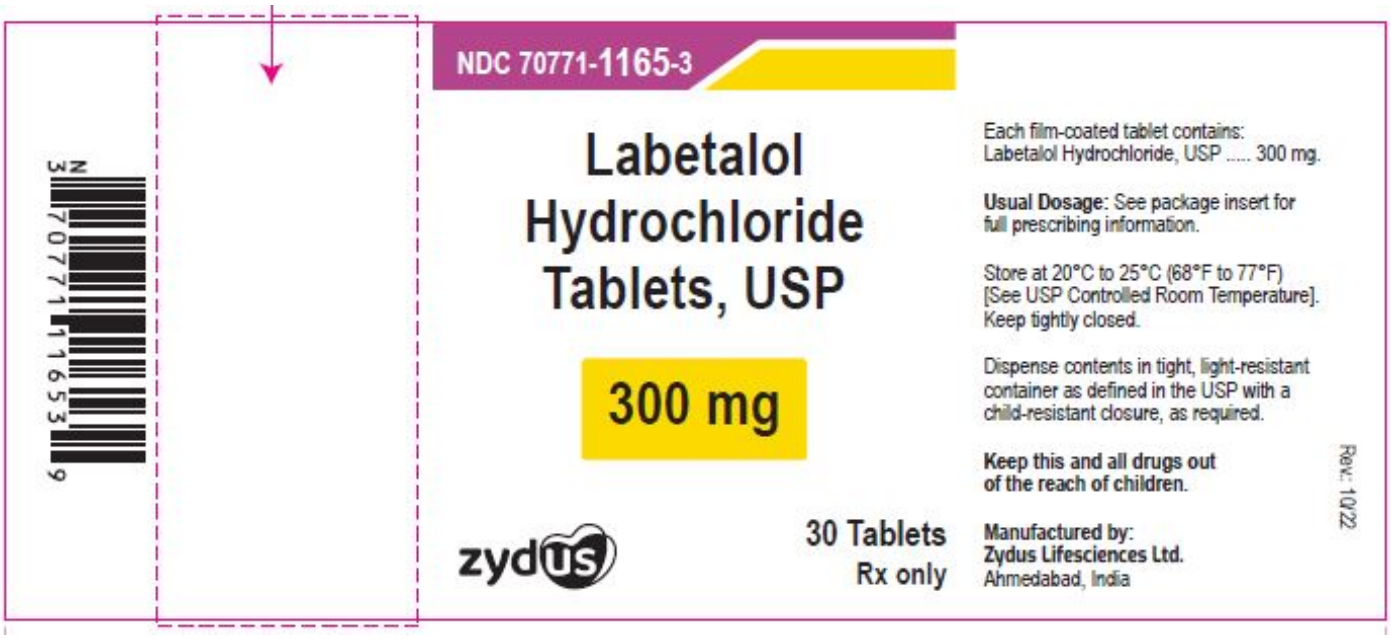


NDC 70771-1165-3

Labetalol hydrochloride tablets, 300 mg

Rx only

30 tablets



LABETALOL HYDROCHLORIDE

labetalol hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1163

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LABETALOL HYDROCHLORIDE (UNII: 1GEV3BAW9J) (LABETALOL - UNII:R5H8897N95)	LABETALOL HYDROCHLORIDE	100 mg

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM OXIDE (UNII: LMI26O6933)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	YELLOW (YELLOW)	**Score**	2 pieces
Shape	ROUND (BICONVEX)	**Size**	8mm
Flavor		**Imprint Code**	7;98
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1163-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2017	
2	NDC:70771-1163-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2017	
3	NDC:70771-1163-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2017	
4	NDC:70771-1163-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207743	12/05/2017	

LABETALOL HYDROCHLORIDE

labetalol hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1164
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LABETALOL HYDROCHLORIDE (UNII: 1GEV3BAW9J) (LABETALOL - UNII:R5H8897N95)	LABETALOL HYDROCHLORIDE	200 mg

Inactive Ingredients	
Ingredient Name	**Strength**
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	WHITE (OFF-WHITE)	**Score**	2 pieces
Shape	ROUND (BICONVEX)	**Size**	11mm
Flavor		**Imprint Code**	7;99
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70771-1164-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2017	
2	NDC:70771-1164-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2017	
3	NDC:70771-1164-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2017	
4	NDC:70771-1164-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

ANDA	ANDA207743	12/05/2017	

LABETALOL HYDROCHLORIDE

labetalol hydrochloride tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1165
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LABETALOL HYDROCHLORIDE (UNII: 1GEV3BAW9J) (LABETALOL - UNII:R5H8897N95)	LABETALOL HYDROCHLORIDE	300 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1--ALUMINUM LAKE (UNII: J9EQA3S2JM)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	GREEN (LIGHT GREEN)	**Score**	no score
Shape	ROUND (BICONVEX)	**Size**	11mm
Flavor		**Imprint Code**	800
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1165-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2017	
2	NDC:70771-1165-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2017	
3	NDC:70771-1165-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2017	
4	NDC:70771-1165-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207743	12/05/2017	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1163, 70771-1164, 70771-1165) , MANUFACTURE(70771-1163, 70771-1164, 70771-1165)

Revised: 10/2022 Zydus Lifesciences Limited