HALOPERIDOL- haloperidol tablet
Zydus Lifesciences Limited

Haloperidol Tablets, USP

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-837-01 in bottle of 100 Tablets

Haloperidol Tablets USP, 0.5 mg

Rx only

100 Tablets

NDC 65841-838-01 in bottle of 100 Tablets

Haloperidol Tablets USP, 1 mg

Rx only

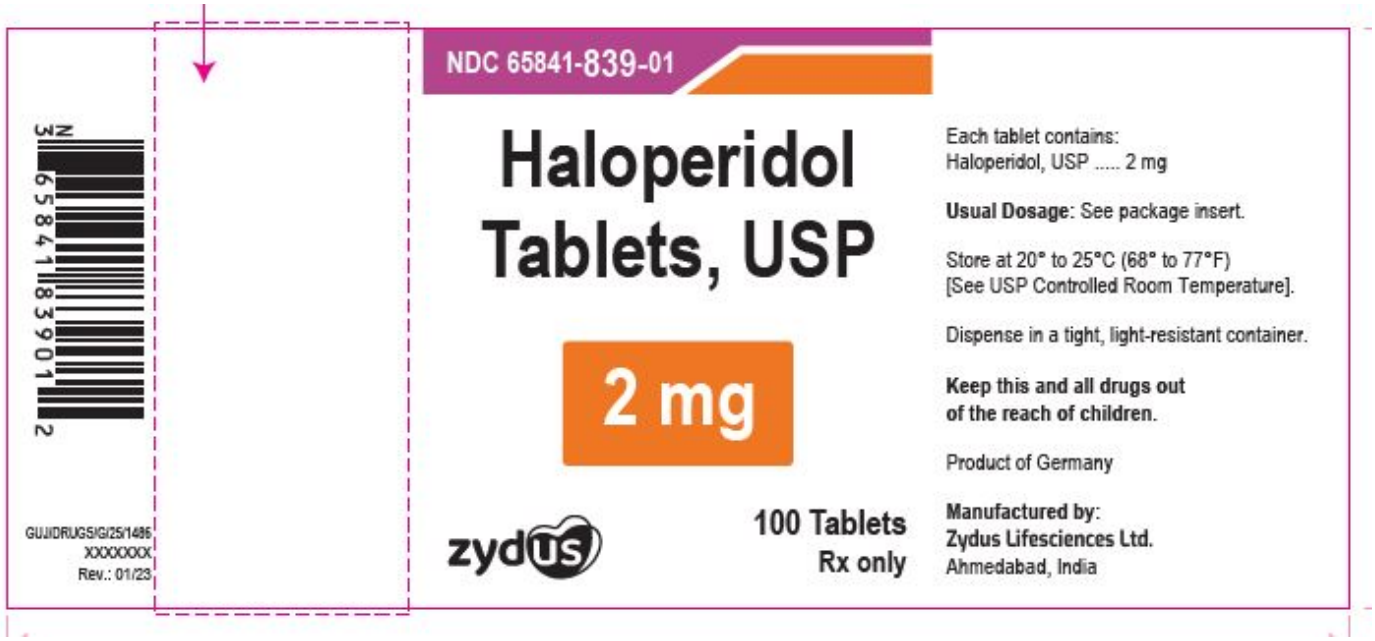
100 Tablets

NDC 65841-839-01 in bottle of 100 Tablets

Haloperidol Tablets USP, 2 mg

Rx only

100 Tablets

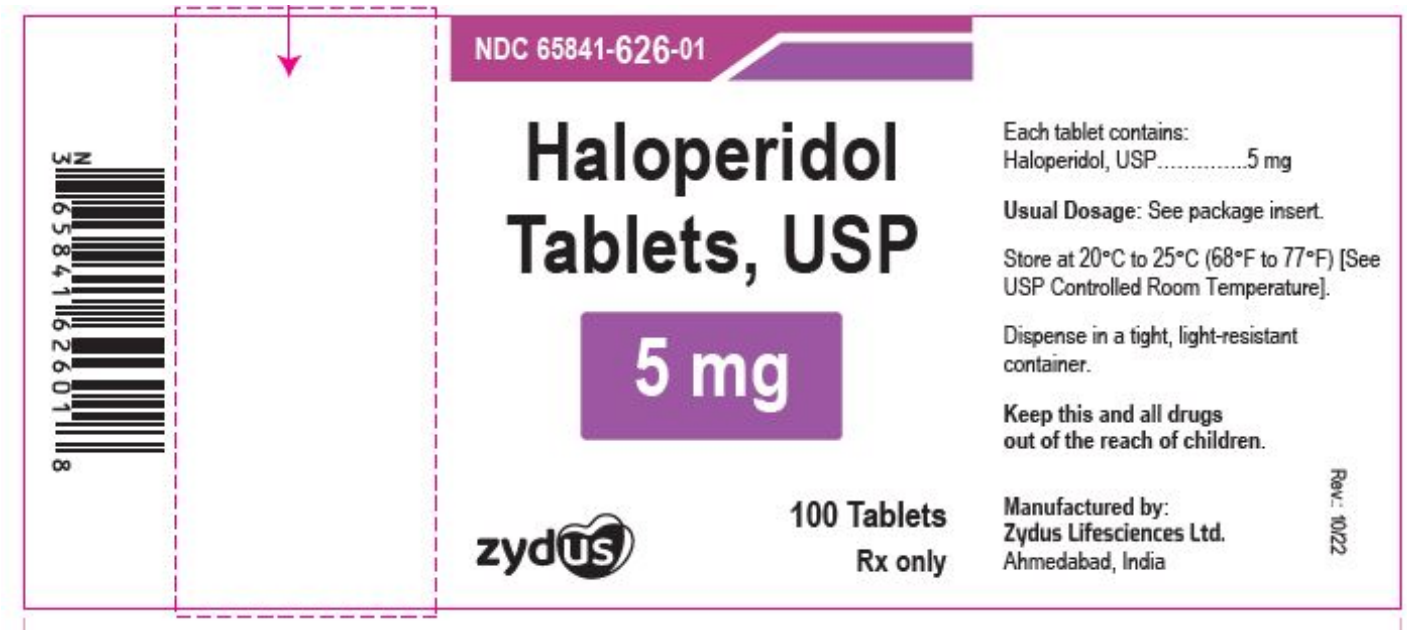


NDC 65841-626-01 in bottle of 100 Tablets

Haloperidol Tablets USP, 5 mg

Rx only

100 Tablets



NDC 65841-627-01 in bottles of 100 tablets

Haloperidol Tablets USP, 10 mg

R_x only

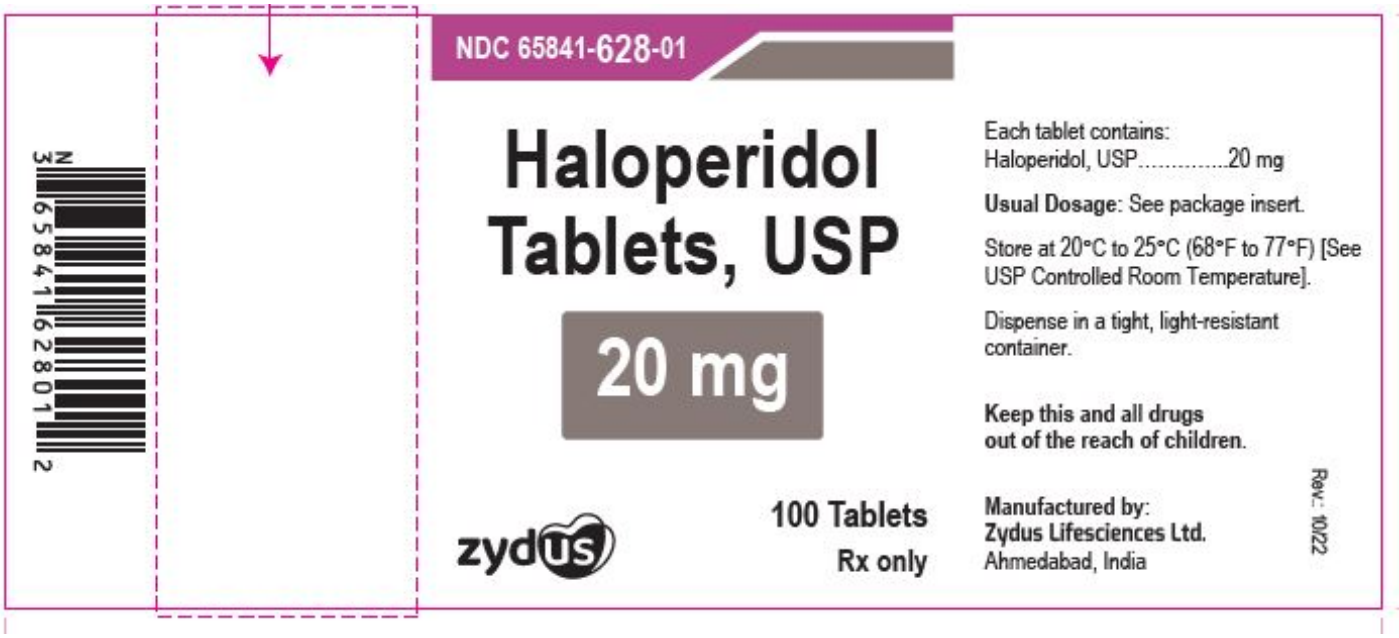
100 Tablets

NDC 65841-628-01 in bottles of 100 tablets

Haloperidol Tablets USP, 20 mg

R_x only

100 Tablets



HALOPERIDOL

haloperidol tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-626
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HALOPERIDOL (UNII: J6292F8L3D) (HALOPERIDOL - UNII:J6292F8L3D)	HALOPERIDOL	5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ALUMINUM OXIDE (UNII: LMI26O6933)	
CALCIUM STEARATE (UNII: 776XM7047L)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	GREEN (GREEN)	**Score**	2 pieces
Shape	OVAL (CAPSULE)	**Size**	10mm

Flavor		**Imprint Code**	ZC;07
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-626-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2008	
2	NDC:65841-626-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2008	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077580	01/03/2008	

HALOPERIDOL

haloperidol tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-627
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HALOPERIDOL (UNII: J6292F8L3D) (HALOPERIDOL - UNII:J6292F8L3D)	HALOPERIDOL	10 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM STEARATE (UNII: 776XM7047L)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	
ALUMINUM OXIDE (UNII: LMI26O6933)	

Product Characteristics

Color	GREEN (LIGHT GREEN)	**Score**	2 pieces
Shape	OVAL (CAPSULE)	**Size**	10mm
Flavor		**Imprint Code**	ZC;08

Contains	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:65841-627-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2008	
2	NDC:65841-627-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2008	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077580	01/03/2008	

HALOPERIDOL

haloperidol tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-628
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HALOPERIDOL (UNII: J6292F8L3D) (HALOPERIDOL - UNII:J6292F8L3D)	HALOPERIDOL	20 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CALCIUM STEARATE (UNII: 776XM7047L)	
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	ORANGE (CORAL)	**Score**	2 pieces
Shape	OVAL (CAPSULE)	**Size**	10mm
Flavor		**Imprint Code**	ZC;09
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-628-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2008	
2	NDC:65841-628-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2008	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077580	01/03/2008	

HALOPERIDOL

haloperidol tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-837
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
HALOPERIDOL (UNII: J6292F8L3D) (HALOPERIDOL - UNII:J6292F8L3D)	HALOPERIDOL	0.5 mg

Inactive Ingredients	
Ingredient Name	Strength
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	WHITE (OFF-WHITE)	**Score**	score with uneven pieces
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	15;11
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:65841-837-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2023	
2	NDC:65841-837-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2023	
3	NDC:65841-837-77	10 in 1 CARTON	02/01/2023	
3	NDC:65841-837-30	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	ANDA077580	02/01/2023	

HALOPERIDOL

haloperidol tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-838
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HALOPERIDOL (UNII: J6292F8L3D) (HALOPERIDOL - UNII:J6292F8L3D)	HALOPERIDOL	1 mg

Inactive Ingredients

Ingredient Name	Strength
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Product Characteristics

Color	WHITE (PALE YELLOW)	**Score**	score with uneven pieces
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	15;12
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-838-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2023	
2	NDC:65841-838-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2023	
3	NDC:65841-838-77	10 in 1 CARTON	02/01/2023	
3	NDC:65841-838-30	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	ANDA077580	02/01/2023	

HALOPERIDOL

haloperidol tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-839
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HALOPERIDOL (UNII: J6292F8L3D) (HALOPERIDOL - UNII:J6292F8L3D)	HALOPERIDOL	2 mg

Inactive Ingredients

Ingredient Name	Strength
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	

Product Characteristics

Color	PINK (Light Pink)	**Score**	score with uneven pieces
Shape	ROUND	**Size**	7mm
Flavor		**Imprint Code**	15;13
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-839-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2023	
2	NDC:65841-839-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2023	
3	NDC:65841-839-77	10 in 1 CARTON	02/01/2023	
3	NDC:65841-839-30	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	ANDA077580	02/01/2023	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(65841-626, 65841-627, 65841-628, 65841-837, 65841-838, 65841-839) , MANUFACTURE(65841-626, 65841-627, 65841-628, 65841-837, 65841-838, 65841-839)

Revised: 11/2024 Zydus Lifesciences Limited