BUSPIRONE HYDROCHLORIDE- buspirone hydrochloride tablet
Zydus Lifesciences Limited

Buspirone Hydrochloride Tablets

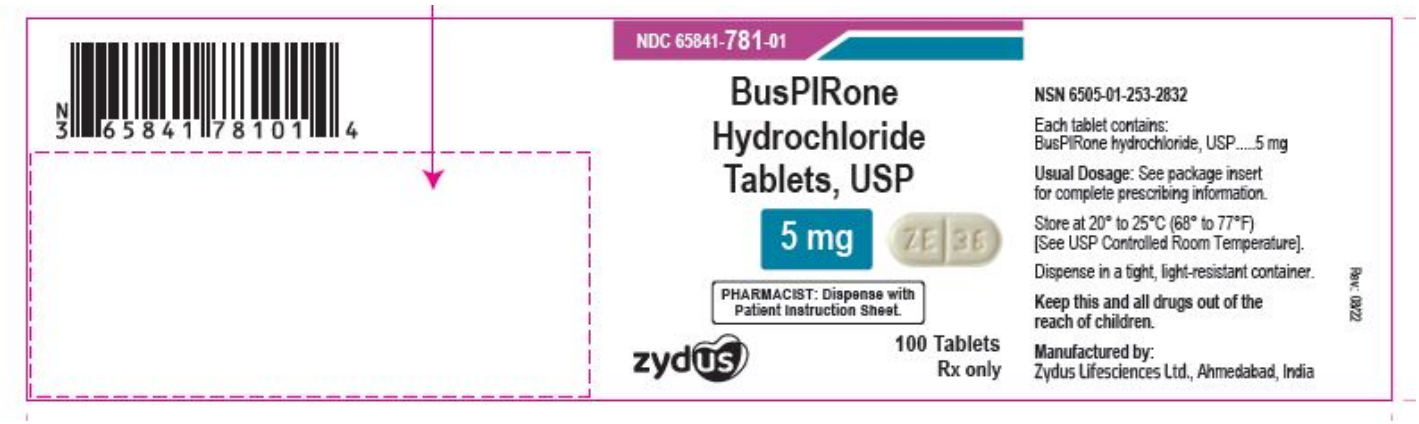
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-781-01 in bottle of 100 tablets

Buspirone Hydrochloride Tablets USP, 5 mg

R_x only

100 tablets

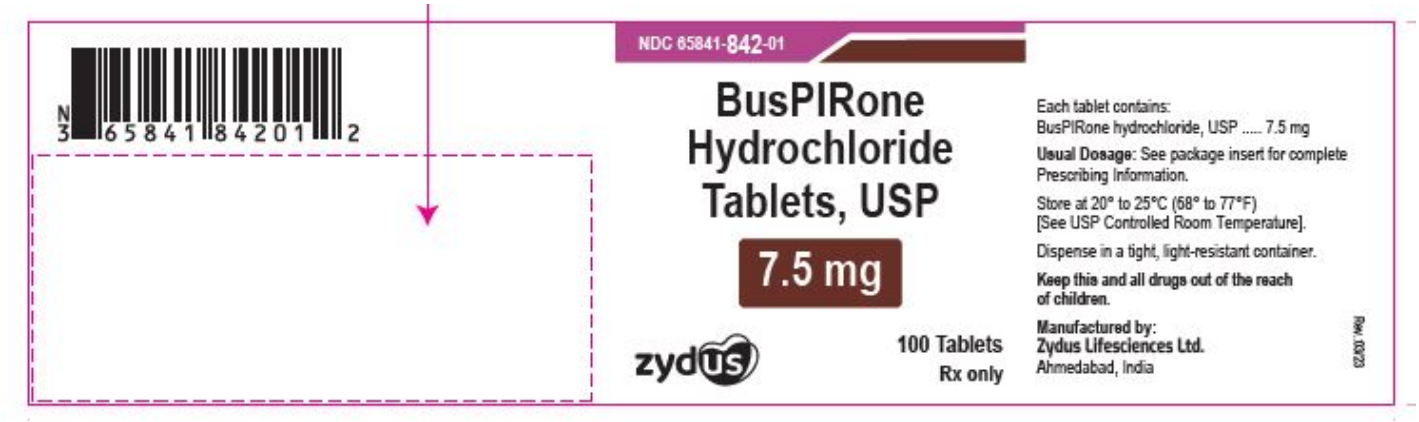


NDC 65841-842-01 in bottle of 100 tablets

Buspirone Hydrochloride Tablets USP, 7.5 mg

R_x only

100 tablets



NDC 65841-782-01 in bottle of 100 tablets

Buspirone Hydrochloride Tablets USP, 10 mg

R_x only

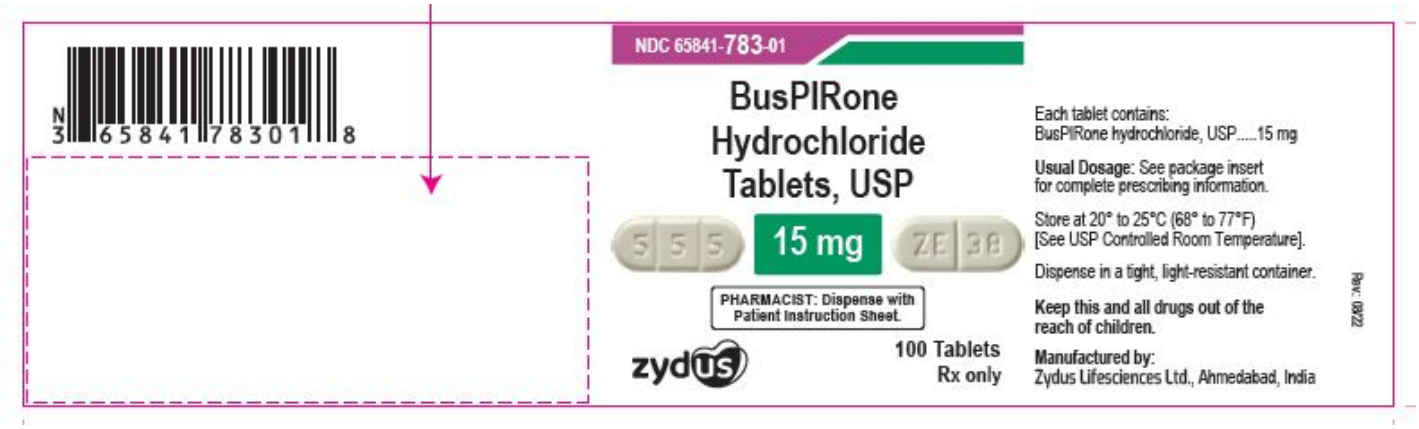
100 tablets

NDC 65841-783-01 in bottle of 100 tablets

Buspirone Hydrochloride Tablets USP, 15 mg

R_x only

100 tablets

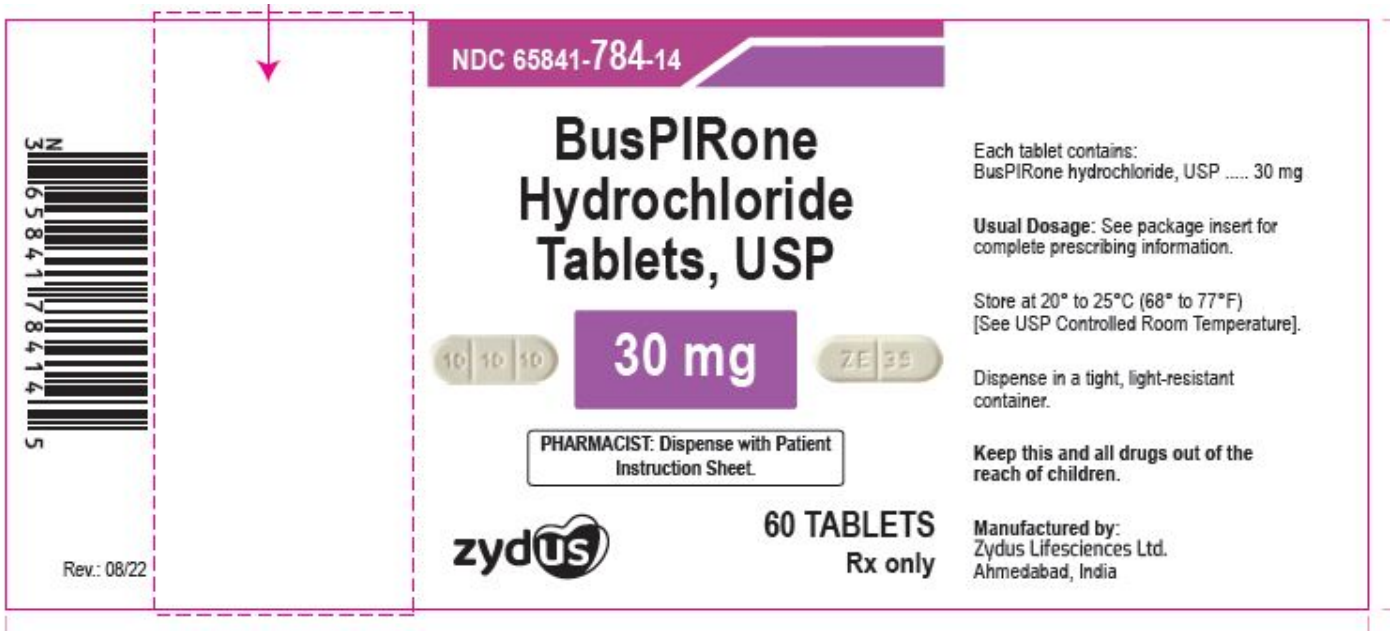


NDC 65841-784-14 in bottle of 60 tablets

Buspirone Hydrochloride Tablets USP, 30 mg

R_x only

60 tablets



BUSPIRONE HYDROCHLORIDE

buspirone hydrochloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-781
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BUSPIRONE HYDROCHLORIDE (UNII: 207LT9J9OC) (BUSPIRONE - UNII:TK65WKS8HL)	BUSPIRONE HYDROCHLORIDE	5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics			
Color	WHITE (white to off-white)	**Score**	2 pieces
Shape	CAPSULE (CAPSULE)	**Size**	8mm
Flavor		**Imprint Code**	ZE;36
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-781-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/03/2014	
2	NDC:65841-781-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	05/03/2014	
3	NDC:65841-781-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	05/03/2014	
4	NDC:65841-781-77	100 in 1 CARTON	05/03/2014	
4	NDC:65841-781-30	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	ANDA078888	05/03/2014	

BUSPIRONE HYDROCHLORIDE

buspirone hydrochloride tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-782
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BUSPIRONE HYDROCHLORIDE (UNII: 207LT9J9OC) (BUSPIRONE - UNII:TK65WKS8HL)	BUSPIRONE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	WHITE (white to off-white)	**Score**	2 pieces
Shape	CAPSULE (CAPSULE)	**Size**	10mm
Flavor		**Imprint Code**	ZE;37
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-782-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/03/2014	
2	NDC:65841-782-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	05/03/2014	
3	NDC:65841-782-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	05/03/2014	
4	NDC:65841-782-77	100 in 1 CARTON	05/03/2014	
4	NDC:65841-782-30	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	ANDA078888	05/03/2014	

BUSPIRONE HYDROCHLORIDE

buspirone hydrochloride tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-783
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BUSPIRONE HYDROCHLORIDE (UNII: 207LT9J9OC) (BUSPIRONE - UNII:TK65WKS8HL)	BUSPIRONE HYDROCHLORIDE	15 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	WHITE (white to off-white)	**Score**	3 pieces
Shape	CAPSULE (CAPSULE)	**Size**	12mm

Flavor		**Imprint Code**	5;ZE;38
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-783-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	05/03/2014	
2	NDC:65841-783-28	180 in 1 BOTTLE; Type 0: Not a Combination Product	05/03/2014	
3	NDC:65841-783-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	05/03/2014	
4	NDC:65841-783-77	100 in 1 CARTON	05/03/2014	
4	NDC:65841-783-30	1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:65841-783-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/03/2014	
6	NDC:65841-783-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	05/03/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078888	05/03/2014	

BUSPIRONE HYDROCHLORIDE

buspirone hydrochloride tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-784
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BUSPIRONE HYDROCHLORIDE (UNII: 207LT9J9OC) (BUSPIRONE - UNII:TK65WKS8HL)	BUSPIRONE HYDROCHLORIDE	30 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics			
Color	WHITE (white to off-white)	**Score**	3 pieces
Shape	CAPSULE (CAPSULE)	**Size**	17mm
Flavor		**Imprint Code**	10;ZE;39
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-784-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	05/03/2014	
2	NDC:65841-784-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	05/03/2014	
3	NDC:65841-784-77	100 in 1 CARTON	05/03/2014	
3	NDC:65841-784-30	1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:65841-784-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	05/03/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078888	05/03/2014	

BUSPIRONE HYDROCHLORIDE

buspirone hydrochloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-842
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BUSPIRONE HYDROCHLORIDE (UNII: 207LT9J9OC) (BUSPIRONE - UNII:TK65WKS8HL)	BUSPIRONE HYDROCHLORIDE	7.5 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	WHITE (white to off-white)	**Score**	2 pieces
Shape	CAPSULE (CAPSULE)	**Size**	9mm
Flavor		**Imprint Code**	6;23
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-842-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/21/2023	
2	NDC:65841-842-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	03/21/2023	
3	NDC:65841-842-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	03/21/2023	
4	NDC:65841-842-30	100 in 1 CARTON	03/21/2023	
4		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	ANDA078888	03/21/2023	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(65841-781, 65841-782, 65841-783, 65841-784, 65841-842) , MANUFACTURE(65841-781, 65841-782, 65841-783, 65841-784, 65841-842)