

# BUSPIRONE HYDROCHLORIDE- bupirone 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<sub>x</sub> only

100 tablets

NDC 65841-781-01

BusPIRone Hydrochloride Tablets, USP

5 mg

PHARMACIST: Dispense with Patient Instruction Sheet.

zydus

100 Tablets Rx only

NSN 6505-01-253-2832

Each tablet contains: BusPIRone hydrochloride, USP.....5 mg

Usual Dosage: See package insert for complete prescribing information.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

Dispense in a tight, light-resistant container.

Keep this and all drugs out of the reach of children.

Manufactured by: Zydus Lifesciences Ltd., Ahmedabad, India

Rev: 08/22

NDC 65841-842-01 in bottle of 100 tablets

Buspirone Hydrochloride Tablets USP, 7.5 mg

R<sub>x</sub> only

100 tablets

NDC 65841-842-01

BusPIRone Hydrochloride Tablets, USP

7.5 mg

zydus

100 Tablets Rx only

Each tablet contains: BusPIRone hydrochloride, USP ..... 7.5 mg

Usual Dosage: See package insert for complete Prescribing Information.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

Dispense in a tight, light-resistant container.

Keep this and all drugs out of the reach of children.

Manufactured by: Zydus Lifesciences Ltd. Ahmedabad, India

Rev: 03/23

NDC 65841-782-01 in bottle of 100 tablets

Buspirone Hydrochloride Tablets USP, 10 mg

R<sub>x</sub> only

100 tablets

NDC 65841-782-01

BusPIRone  
Hydrochloride  
Tablets, USP

10 mg

PHARMACIST: Dispense with  
Patient Instruction Sheet.

zydus

100 Tablets  
Rx only

NSN 6505-01-267-3449

Each tablet contains:  
BusPIRone hydrochloride, USP.....10 mg

Usual Dosage: See package insert  
for complete prescribing information.

Store at 20° to 25°C (68° to 77°F)  
[See USP Controlled Room Temperature].

Dispense in a tight, light-resistant container.

Keep this and all drugs out of the  
reach of children.

Manufactured by:  
Zydus Lifesciences Ltd., Ahmedabad, India

Rev: 08/22

NDC 65841-783-01 in bottle of 100 tablets

Buspirone Hydrochloride Tablets USP, 15 mg

R<sub>x</sub> only

100 tablets

NDC 65841-783-01

BusPIRone  
Hydrochloride  
Tablets, USP

15 mg

PHARMACIST: Dispense with  
Patient Instruction Sheet.

zydus

100 Tablets  
Rx only

Each tablet contains:  
BusPIRone hydrochloride, USP.....15 mg

Usual Dosage: See package insert  
for complete prescribing information.

Store at 20° to 25°C (68° to 77°F)  
[See USP Controlled Room Temperature].

Dispense in a tight, light-resistant container.

Keep this and all drugs out of the  
reach of children.

Manufactured by:  
Zydus Lifesciences Ltd., Ahmedabad, India

Rev: 08/22

NDC 65841-784-14 in bottle of 60 tablets

Buspirone Hydrochloride Tablets USP, 30 mg

R<sub>x</sub> only

60 tablets

NDC 65841-784-14



Rev.: 08/22


# BusPIRone Hydrochloride Tablets, USP



30 mg



PHARMACIST: Dispense with Patient Instruction Sheet.



Each tablet contains:  
BusPIRone hydrochloride, USP ..... 30 mg

**Usual Dosage:** See package insert for complete prescribing information.

Store at 20° to 25°C (68° to 77°F)  
[See USP Controlled Room Temperature].

Dispense in a tight, light-resistant container.

**Keep this and all drugs out of the reach of children.**

Manufactured by:  
Zydus Lifesciences Ltd.  
Ahmedabad, India

**60 TABLETS**  
Rx only

## BUSPIRONE HYDROCHLORIDE

buspirone hydrochloride tablet

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:65841-781
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BUSPIRONE HYDROCHLORIDE</b> (UNII: 207LT9J9OC) (BUSPIRONE - UNII:TK65WKS8HL)	BUSPIRONE HYDROCHLORIDE	5 mg

### Inactive Ingredients

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

### Product Characteristics

<b>Color</b>	WHITE (white to off-white)	<b>Score</b>	2 pieces
<b>Shape</b>	CAPSULE (CAPSULE)	<b>Size</b>	8mm
<b>Flavor</b>		<b>Imprint Code</b>	ZE;36
<b>Contains</b>			

## 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

bupirone hydrochloride tablet

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:65841-783
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

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

### Product Characteristics

<b>Color</b>	WHITE (white to off-white)	<b>Score</b>	3 pieces
<b>Shape</b>	CAPSULE (CAPSULE)	<b>Size</b>	12mm

<b>Flavor</b>		<b>Imprint Code</b>	5;ZE;38	
<b>Contains</b>				
<b>Packaging</b>				
#	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	
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA078888	05/03/2014		

## BUSPIRONE HYDROCHLORIDE

buspirone hydrochloride tablet

<b>Product Information</b>			
<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:65841-784
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
Ingredient Name	Basis of Strength	Strength	
<b>BUSPIRONE HYDROCHLORIDE</b> (UNII: 207LT9J9OC) (BUSPIRONE - UNII:TK65WKS8HL)	BUSPIRONE HYDROCHLORIDE	30 mg	
<b>Inactive Ingredients</b>			
Ingredient Name	Strength		
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)			
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)			
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)			
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)			
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)			

## Product Characteristics

<b>Color</b>	WHITE (white to off-white)	<b>Score</b>	3 pieces
<b>Shape</b>	CAPSULE (CAPSULE)	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	10;ZE;39
<b>Contains</b>			

## 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		

## Marketing Information

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

## BUSPIRONE HYDROCHLORIDE

bupirone hydrochloride tablet

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:65841-842
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	

**SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)**

### Product Characteristics

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

### 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)

Revised: 11/2024

Zydus Lifesciences Limited