

BUSPIRONE HYDROCHLORIDE - buspirone hydrochloride tablet

Zydus Lifesciences Limited

Buspirone Hydrochloride Tablets

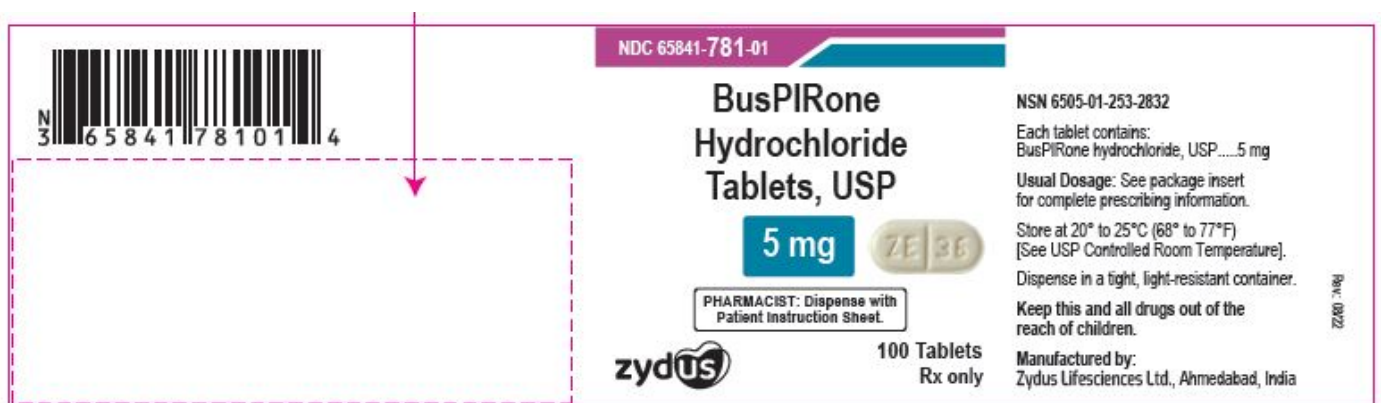
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

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 65841-782-01

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_x 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_x only

60 tablets

NDC 65841-784-14



Rev.: 08/22

BusPIRone Hydrochloride Tablets, USP



30 mg



PHARMACIST: Dispense with Patient Instruction Sheet.



60 TABLETS
 Rx only

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

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

bupirone 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 | | |

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

| | | | |
|--------------------------------|-------------------------|---------------------------|---------------|
| 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) |

Revised: 3/2023

Zydus Lifesciences Limited