

DOXAZOSIN - doxazosin tablet
Zydus Lifesciences Limited

DOXAZOSIN TABLETS

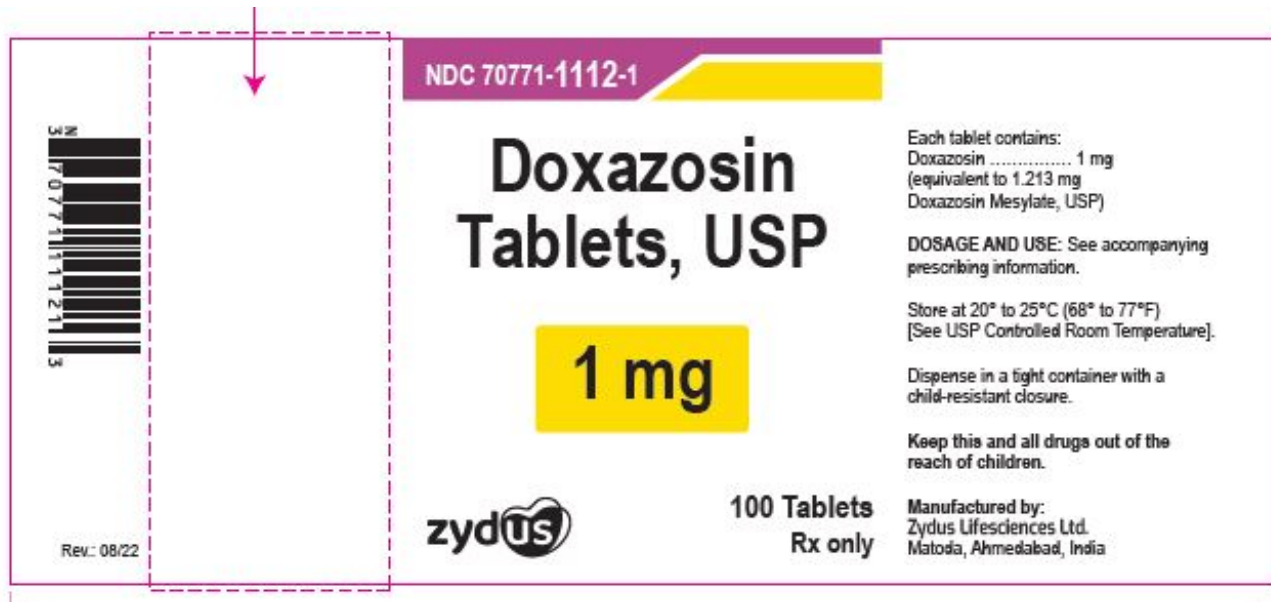
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1112-1 in bottle of 100 Tablets

Doxazosin Tablets USP, 1 mg

Rx only

100 Tablets



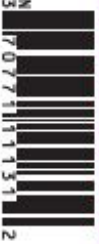
NDC 70771-1113-1 in bottle of 100 Tablets

Doxazosin Tablets USP, 2 mg

Rx only

100 Tablets

NDC 70771-1113-1



**Doxazosin
Tablets, USP**

2 mg

zydUS

100 Tablets
Rx only

Rev.: 08/22

Each tablet contains:
Doxazosin 2 mg
(equivalent to 2.426 mg
Doxazosin Mesylate, USP)

DOSAGE AND USE: See accompanying
prescribing information.

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

Dispense in a tight container with a
child-resistant closure.

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

Manufactured by:
Zydus Lifesciences Ltd.
Matoda, Ahmedabad, India

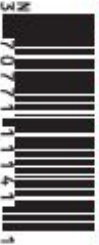
NDC 70771-1114-1 in bottle of 100 Tablets

Doxazosin Tablets USP, 4 mg

Rx only

100 Tablets

NDC 70771-1114-1



**Doxazosin
Tablets, USP**

4 mg

zydUS

100 Tablets
Rx only

Rev.: 08/22

Each tablet contains:
Doxazosin 4 mg
(equivalent to 4.852 mg
Doxazosin Mesylate, USP)

DOSAGE AND USE: See accompanying
prescribing information.

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

Dispense in a tight container with a
child-resistant closure.

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

Manufactured by:
Zydus Lifesciences Ltd.
Matoda, Ahmedabad, India


NDC 70771-1115-1 in bottle of 100 Tablets

Doxazosin Tablets USP, 8 mg

Rx only

100 Tablets

NDC 70771-1115-1



0428
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0

Doxazosin Tablets, USP

8 mg

Each tablet contains:
Doxazosin 8 mg
(equivalent to 9.703 mg
Doxazosin Mesylate, USP)


DOSAGE AND USE: See accompanying
prescribing information.

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

Dispense in a tight container with a
child-resistant closure.

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

Rev.: 08/22



100 Tablets
Rx only

Manufactured by:
Zydus Lifesciences Ltd.
Matoda, Ahmedabad, India

DOXAZOSIN

doxazosin tablet

Product Information

| | | | |
|--------------------------------|-------------------------|---------------------------|----------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:70771-1112 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| DOXAZOSIN MESYLATE (UNII: 86P6PQK0MU) (DOXAZOSIN - UNII:NW1291F1W8) | DOXAZOSIN | 1 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) | |

Product Characteristics

| | | | |
|-----------------|----------------------------|---------------------|----------|
| Color | WHITE (WHITE TO OFF-WHITE) | Score | 2 pieces |
| Shape | ROUND (ROUND BICONVEX) | Size | 7mm |
| Flavor | | Imprint Code | 783 |
| Contains | | | |

Packaging

| | | | |
|--|--|------------------------|----------------------|
| | | Marketing Start | Marketing End |
|--|--|------------------------|----------------------|

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:70771-1112-3 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 08/31/2017 | |
| 2 | NDC:70771-1112-1 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 08/31/2017 | |
| 3 | NDC:70771-1112-0 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 08/31/2017 | |
| 4 | NDC:70771-1112-4 | 10 in 1 CARTON | 08/31/2017 | |
| 4 | NDC:70771-1112-2 | 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 | ANDA208719 | 08/31/2017 | |

DOXAZOSIN

doxazosin tablet

Product Information

| | | | |
|-------------------------|-------------------------|--------------------|----------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:70771-1113 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------|
| DOXAZOSIN MESYLATE (UNII: 86P6PQK0MU) (DOXAZOSIN - UNII:NW1291F1W8) | DOXAZOSIN | 2 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) | |

Product Characteristics

| | | | |
|----------|---------------------------|--------------|----------|
| Color | PINK (LIGHT PINK TO PINK) | Score | 2 pieces |
| Shape | ROUND (ROUND BICONVEX) | Size | 7mm |
| Flavor | | Imprint Code | 784 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:70771-1113-3 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 08/31/2017 | |
| 2 | NDC:70771-1113-1 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 08/31/2017 | |
| 3 | NDC:70771-1113-0 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 08/31/2017 | |
| 4 | NDC:70771-1113-4 | 10 in 1 CARTON | 08/31/2017 | |
| 4 | NDC:70771-1113-2 | 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 | ANDA208719 | 08/31/2017 | |

DOXAZOSIN

doxazosin tablet

Product Information

| | | | |
|-------------------------|-------------------------|--------------------|----------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:70771-1114 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------|
| DOXAZOSIN MESYLATE (UNII: 86P6PQK0MU) (DOXAZOSIN - UNII:NW1291F1W8) | DOXAZOSIN | 4 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) | |

Product Characteristics

| | | | |
|--------|-----------------------------|--------------|----------|
| Color | PINK (LIGHT PINK TO PINK) | Score | 2 pieces |
| Shape | CAPSULE (CAPSULE, BICONVEX) | Size | 12mm |
| Flavor | | Imprint Code | 785 |

Contains**Packaging**

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:70771-1114-3 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 08/31/2017 | |
| 2 | NDC:70771-1114-1 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 08/31/2017 | |
| 3 | NDC:70771-1114-0 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 08/31/2017 | |
| 4 | NDC:70771-1114-4 | 10 in 1 CARTON | 08/31/2017 | |
| 4 | NDC:70771-1114-2 | 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 | ANDA208719 | 08/31/2017 | |

DOXAZOSIN

doxazosin tablet

Product Information

| | | | |
|--------------------------------|-------------------------|---------------------------|----------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:70771-1115 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| DOXAZOSIN MESYLATE (UNII: 86P6PQK0MU) (DOXAZOSIN - UNII:NW1291F1W8) | DOXAZOSIN | 8 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| FD&C BLUE NO. 2 (UNII: L06K8R7DQK) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) | |

Product Characteristics

| | | | |
|-----------------|---------------------------------|---------------------|----------|
| Color | PURPLE (LIGHT PURPLE TO PURPLE) | Score | 2 pieces |
| Shape | ROUND (ROUND BICONVEX) | Size | 9mm |
| Flavor | | Imprint Code | 786 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:70771-1115-3 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 08/31/2017 | |
| 2 | NDC:70771-1115-0 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 08/31/2017 | |
| 3 | NDC:70771-1115-4 | 10 in 1 CARTON | 08/31/2017 | |
| 3 | NDC:70771-1115-2 | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 4 | NDC:70771-1115-1 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 08/31/2017 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA208719 | 08/31/2017 | |

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------------|---------|-----------|---|
| Zydus Lifesciences Limited | | 863362789 | ANALYSIS(70771-1112, 70771-1113, 70771-1114, 70771-1115) , MANUFACTURE(70771-1112, 70771-1113, 70771-1114, 70771-1115) |

Revised: 8/2022

Zydus Lifesciences Limited