

**CLONIDINE HYDROCHLORIDE- clonidine hydrochloride tablet
DirectRX**

CLONIDINE HYDROCHLORIDE

SPL Unclassified

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Description

-

Clinical Pharmacology

-

Indications and Usage

-

Contraindications

-

Warnings

-

Precautions

-

Adverse Reactions

-

Overdosage

-

Dosage and Administration

-

How Supplied

-

Package Label

D

CLONIDINE HYDROCHLORIDE
0.3mg 60 Tabs

Generic For: **CATAPRESS**
 Each Tablet Contains: Clonidine Hydrochloride, USP 0.3mg

Lot# Prod# 268-60 Discard After: 04/17

Packaged and Distributed By: **DIRECT Rx** Alpharetta, GA 30005

Mfg Lot: 12/30/2016

Mfg By: **Unichem Pharm., USA Inc.**
 Rochelle Park, NJ 07662
 NDC 29300-137-05

M

May cause DROWSINESS. ALCOHOL may INTENSIFY this effect. Use care when operating dangerous machinery.

CLONIDINE HYDROCHLORIDE 0.3m
 NDC 61919-268-60 60 Tab
 Lot Exp Date 04/17
 Mfg NDC 29300-137-05

CLONIDINE HYDROCHLORIDE 0.3m
 NDC 61919-268-60 60 Tab
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CLONIDINE HYDROCHLORIDE 0.3m
 NDC 61919-268-60 60 Tab
 Lot Exp Date 04/17
 Mfg NDC 29300-137-05

AEOZT
 Caution: Federal law prohibits transfer of this drug to any person other than the patient for whom it was prescribed.
RX ONLY-KEEP OUT OF REACH OF CHILDREN
 Dosage: See package insert. Store between 68-77 degrees F

D

CLONIDINE HYDROCHLORIDE
0.1mg 90 Tabs

Generic For: **CATAPRES**
 Each tablet contains: Clonidine Hydrochloride USP 0.1 mg

Lot# Prod# 605-90 Discard After: 11/19

Packaged and Distributed By: **DIRECT Rx** Alpharetta, GA 30005

Mfg Lot: 6/18/2018

Mfg For: **Almobic Pharmaceuticals, Inc.**
 Bridgewater, NJ 08807
 NDC 62332-054-71

M

May cause DROWSINESS. ALCOHOL may INTENSIFY this effect. Use care when operating dangerous machinery.

CLONIDINE HYDROCHLORIDE 0.1m
 NDC 61919-605-90 90 Tabs
 Lot Exp Date 11/19
 Mfg NDC 62332-054-71

CLONIDINE HYDROCHLORIDE 0.1m
 NDC 61919-605-90 90 Tabs
 Lot Exp Date 11/19
 Mfg NDC 62332-054-71

CLONIDINE HYDROCHLORIDE 0.1m
 NDC 61919-605-90 90 Tabs
 Lot Exp Date 11/19
 Mfg NDC 62332-054-71

CLONIDINE HYDROCHLORIDE 0.1m
 NDC 61919-605-90 90 Tabs
 Lot Exp Date 11/19
 Mfg NDC 62332-054-71

A00D5
 Caution: Federal law prohibits transfer of this drug to any person other than the patient for whom it was prescribed.
RX ONLY-KEEP OUT OF REACH OF CHILDREN
 Dosage: See package insert. Store between 68-77 degrees F

CLONIDINE HYDROCHLORIDE

clonidine hydrochloride tablet

Product Information

| | | | |
|-------------------------|-------------------------|--------------------|------------------------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:61919-268(NDC:29300-137) |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------------|----------|
| CLONIDINE HYDROCHLORIDE (UNII: W7616XXF06) (CLONIDINE - UNII:MN3L5RMN02) | CLONIDINE HYDROCHLORIDE | 0.3 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| POVIDONE K29/32 (UNII: 390RMW2PEQ) | |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | |

| | |
|--|--|
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |

Product Characteristics

| | | | |
|----------|-------|--------------|----------|
| Color | white | Score | 2 pieces |
| Shape | OVAL | Size | 10mm |
| Flavor | | Imprint Code | U;137 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:61919-268-60 | 60 in 1 BOTTLE; Type 0: Not a Combination Product | 12/29/2015 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA078895 | 12/29/2015 | |

CLONIDINE HYDROCHLORIDE

clonidine hydrochloride tablet

Product Information

| | | | |
|-------------------------|-------------------------|--------------------|------------------------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:61919-605(NDC:62332-054) |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------------|----------|
| CLONIDINE HYDROCHLORIDE (UNII: W76I6XXF06) (CLONIDINE - UNII:MN3L5RMN02) | CLONIDINE HYDROCHLORIDE | 0.1 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | |
| SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD) | |

ALUMINUM OXIDE (UNII: LM26O6933)

Product Characteristics

| | | | |
|-----------------|----------------------|---------------------|----------|
| Color | brown (Light Tan) | Score | 2 pieces |
| Shape | OVAL (Oval,Biconvex) | Size | 7mm |
| Flavor | | Imprint Code | L167 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:61919-605-90 | 90 in 1 BOTTLE; Type 0: Not a Combination Product | 04/04/2019 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA091368 | 04/04/2019 | |

Labeler - DirectRX (079254320)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------|---------|-----------|------------------------------|
| DirectRX | | 079254320 | repack(61919-268, 61919-605) |

Revised: 4/2019

DirectRX