

**ALFUZOSIN HYDROCHLORIDE- alfuzosin hydrochloride tablet, extended release
DirectRX**

ALFUZOSIN HYDROCHLORIDE

Indications and Usage

-

Dosage and Administration

-

Dosage forms and Strengths

-

Contraindications

-

Warnings and Precautions

-

Adverse Reactions

-

Drug Interactions

-

Use in Specific Populations

-

Overdosage

-

Description

-

Clinical Pharmacology

-

Nonclinical Toxicology

-

Clinical Studies

-

How Supplied

-

Patient Counseling Information

-

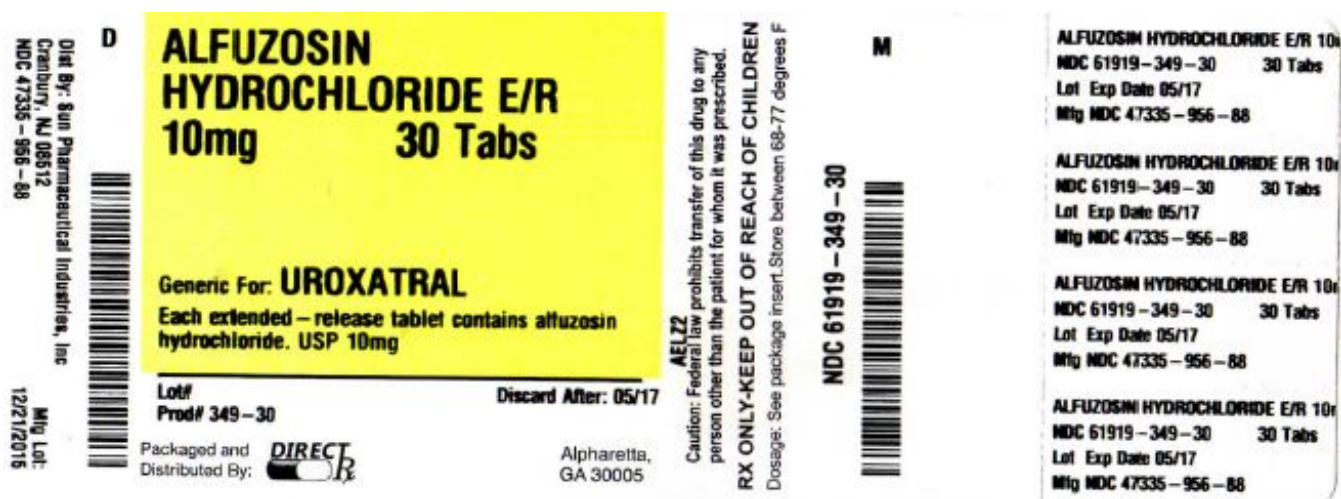
Patient Information

-

SPL Unclassified

-

Package Label



ALFUZOSIN HYDROCHLORIDE

alfuzosin hydrochloride tablet, extended release

Product Information

| | | | |
|-------------------------|-------------------------|--------------------|------------------------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:61919-349(NDC:47335-956) |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------------|----------|
| ALFUZOSIN HYDROCHLORIDE (UNII: 75046A1XTN) (ALFUZOSIN - UNII:90347YTW5F) | ALFUZOSIN HYDROCHLORIDE | 10 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| STARCH, CORN (UNII: O8232NY3SJ) | |
| HYPROMELLOSES (UNII: 3NXW29V3WO) | |
| DIMETHYLAMINOETHYL METHACRYLATE - BUTYL METHACRYLATE - METHYL METHACRYLATE | |

| | |
|--|--|
| COPOLYMER (UNII: 905HNO1S1H) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| TALC (UNII: 7SEV7J4R1U) | |
| HYDROXYPROPYL CELLULOSE (TYPE H) (UNII: RFW2ET671P) | |

Product Characteristics

| | | | |
|-----------------|----------------------------|---------------------|----------|
| Color | white (white to off-white) | Score | no score |
| Shape | ROUND | Size | 10 mm |
| Flavor | | Imprint Code | 956 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:61919-349-30 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 12/21/2015 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA079057 | 12/21/2015 | |

Labeler - DirectRX (079254320)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------|---------|-----------|---------------------|
| DirectRX | | 079254320 | repack(61919-349) |

Revised: 12/2015

DirectRX