InvaGen Pharmaceuticals, Inc.

SAFETY DATA SHEET

Alfuzosin Hydrochloride Extended-Release Tablets

1. IDENTIFICATION

Manufacturer:

InvaGen Pharmaceuticals Inc
7, Oser Avenue
Hauppauge, NY 11788

Emergency Phone:

1-631-231-3233

Common Name: Alfuzosin Hydrochloride Extended-Released Tablets

Chemical Family: Quinazoline derivative

Synonym(s): Alfusosine

Chemical Name: 2-Furancarboxamide, (+/-)-N-[3-[(4-amino-6,7-dimethoxy-2-quinazolinyl)methylamino]propyl]tetrahydro-, monohydrochloride

Trade Name(s): Alfuzosin Hydrochloride Extended-Release Tables 10mg

Therapeutic Category: an alpha1-adrenoreceptor-antagonist

Molecular formula: $C_{19}H_{27}N_5O_4$.HCl and **Molecular Weight:** 425.91

2.HAZARDS IDENTIFICATION

Not considered hazardous when handled under normal conditions.

EMERGENCY OVERVIEW

Caution Statement: Each Alfuzosin Hydrochloride Extended – Release Tablets intended for oral administration contains Alfuzosin Hydrochloride and excipients generally considered to be non-toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

Routes of Entry: Oral

Effects of Overexposure: Tablets are intended for human consumption under guidance of a physician. Intact tablets are not considered hazardous under normal handling procedures.

Medical conditions Aggravated by Long Term Exposure:

No Data Available.

Carcinogenicity: Alfuzosin Hydrochloride - Not listed by IARC, NTP and OSHA.

3.COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS #	Concentration %
		10 mg
Alfuzosin Hydrochloride	81403-68-1	≈ 2.85%
Excipients	NA	≈ 97.15%

Contains no hazardous components (one percent or greater) or carcinogens (one-tenth percent or greater) not listed above.

* All Concentrations are percent by weight.

4. FIRST AID MEASURES

Inhalation: Move in to fresh air and keep at rest. For breathing difficulties, Oxygen may be necessary. Get medical attention. If breathing stops, provide artificial respiration.

Skin Contact: Wash skin thoroughly with soap and water. Get medical attention if irritation persists after washing. Remove contaminated clothing and shoes. Wash contaminated clothing before reuse. Destroy or thoroughly clean contaminated shoes.

Eye Contact: Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

Ingestion: Do not induce vomiting unless directed to do so by medical personnel. Never give liquid to an unconscious person. Get medical attention.

Notes to the Physician:
Alfuzosin is a selective antagonist of post-synaptic alpha1-adrenoreceptors, which are located in the prostate, bladder base, bladder neck, prostatic capsule, and prostatic urethra.

Overdose Treatment:
Should overdose of Alfuzosin hydrochloride lead to hypotension, support of the cardiovascular system is of first importance. Restoration of blood pressure and normalization of heart rate may be accomplished by keeping the patient in the supine position. If this measure is inadequate, then the administration of intravenous fluids should be considered. If necessary, vasopressors should then be used, and the renal function should be monitored and supported as needed. Alfuzosin is 82% to 90% protein bound; therefore, dialysis may not be of benefit.

5.FIRE-FIGHTING MEASURES

Extinguishing Media: Water spray, CO2, dry chemical or alcohol resistant foam.

Unusual Fire & Explosion Hazards: Emits toxic fumes under fire conditions.

Special Fire Fighting Procedures: Self-Contained breathing apparatus and full protective clothing must be worn in case of fire.

Protective Measures: Prevent runoff from fire control or dilution from entering streams, sewers, or drinking water supply.

6.ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment. Immediately contact emergency personnel. Keep unnecessary personnel away. Follow all firefighting procedures.

Environmental precautions: Do not release in to the environment.

Spill Cleanup methods: Use a vacuum cleaner. If not possible, moisten dust with water before it is collected with shovel, broom or the like. Collect in containers and seal securely. For waste disposal, see section 13 of the SDS.

7.HANDLING AND STORAGE

Handling: Do not breathe dust. Avoid contact with eyes, skin, and clothing. Wash thoroughly after handling.

Storage: Keep container tightly closed in a cool, well-ventilated place. Keep away from heat and direct sun light.

8.EXPOSURE CONTROLS / PERSONAL PROTECTION

Compressed tablets are not considered hazardous under normal handling procedures and protective equipment is not required. The following are recommended for manufacturing or other situations where exposure to the powder may occur.

Protective Measures: Minimize open handling. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas.

Respiratory Protection: Use a NIOSH approved respirator or an alternate approved dust mask should be used.

Hand Protection: Chemical resistant gloves.

Eye Protection: Wear safety glasses with side shields (or goggles). If the work environment or activity involves dusty conditions, mist or aerosols, wear the appropriate goggles. Wear a face shield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and Body Protection: Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

Hygiene Measures: Wash skin thoroughly with soap and water.

9.PHYSICAL AND CHEMICAL PROPERTIES

Physical Properties:

Physical State: Solid

Form: Tablets

Appearance:
10 mg Tablets: Off White round biconvex tablets debossed with 'IG' on one side and '302' on the other.

10. STABILITY AND REACTIVITY

Possibility of hazardous reactions: Stable under ordinary conditions of use and storage.

Conditions to avoid: Excessive heat & Moisture.

Incompatible materials: Strong oxidizers, Strong Bases and Strong Acids.

Hazardous Decomposition products: Thermal decomposition or combustion may liberate irritating gases like Carbon oxides (CO, CO2) or vapors.

11.TOXICOLOGICAL INFORMATION

General information: The information presented below pertains to the individual ingredients (Alfuzosin Hydrochloride), and not to the mixture(s) or final formulations.

Inhalation: No data available

Ingestion: No data available

Skin Corrosion/ irritation: No data available.

Serious eye damage/eye irritation: No data available.

Respiratory sensitizer/Skin sensitizer: No data available.

Carcinogenicity: There was no evidence of a drug-related increase in the incidence of tumors in mice following dietary administration of 100 mg/kg/day Alfuzosin for 98 weeks (13 and 15 times the maximum recommended human dose [MRHD] of 10 mg based on AUC of unbound drug), in females and males, respectively. The highest dose tested in female mice may not have constituted a maximally tolerated dose. Likewise, there was no evidence of a drug-related increase in the incidence of tumors in rats following dietary administration of 100 mg/kg/day Alfuzosin for 104 weeks (53 and 37 times the MRHD in females and males, respectively).

Mutagenesis: Alfuzosin showed no evidence of mutagenic effect in the Ames and mouse lymphoma assays, and was free of any clastogenic effects in the Chinese hamster ovary cell and in vivo mouse micronucleus assays. Alfuzosin treatment did not induce DNA repair in a human cell line.

Reproductive Toxicity: There was no evidence of reproductive organ toxicity when male rats were administered oral doses of several hundred times (250 mg/kg/day for 26 weeks) the MRHD of Alfuzosin. No impairment of fertility was observed following oral (gavage) administration to male rats at doses of up to 125 mg/kg/day for 70 days. Estrous cycling was inhibited in rats and dogs at approximately 12 and 18 times the MRHD respectively (doses of 25 mg/kg and 20 mg/kg, respectively), but did not result in impaired fertility in female rats.

Other information:
The following adverse reactions have been identified during post approval use of Alfuzosin hydrochloride. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

General disorders: edema
Cardiac disorders: tachycardia, chest pain, angina pectoris in patients with pre-existing coronary artery disease, atrial fibrillation
Gastrointestinal disorders: diarrhea
Hepatobiliary disorders: hepatocellular and cholestatic liver injury (including cases with jaundice leading to drug discontinuation)
Respiratory system disorders: rhinitis
Reproductive system disorders: priapism
Skin and subcutaneous tissue disorders: rash, pruritis, urticaria, angioedema
Vascular disorders: flushing

12.ECOLOGICAL INFORMATION

General information: The information presented below pertains to the individual ingredients (Alfuzosin Hydrochloride), and not to the mixture(s) or final formulations.

Ecotoxicity Effects:
Acute toxicity to Fish: No data available.
Acute toxicity to Aquatic Invertebrates: No data available.
Toxicity to Aquatic Plants: No data available.
Bioaccumulation: No data available.
Mobility: No data available.

13.DISPOSAL CONSIDERATIONS

Waste Disposal: Dispose of waste must be in accordance with all applicable Federal, State and local laws.

Measures for Avoidance and Recovery: Incineration is the most effective method of disposal in most instances. Do not allow runoff to sewer, waterway or ground. Operations that involve the crushing or shredding of waste materials or returned goods should take into account recommended exposure limits where they exist.

14.TRANSPORT INFORMATION

DOT: Not Regulated

IMDG: Not regulated

ICAO/IATA: Not Regulated

IMO: Not Regulated

15.REGULATORY INFORMATION

Stated regulatory information chosen primarily for possible usage of InvaGen Pharmaceutical, Inc. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

CERLA Hazardous Substance List (40 CFR 302.4): None
TSCA : None

SARA Title III
Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A): None
Section 313 Toxic Release Inventory (40 CFR 372): None

16.OTHER INFORMATION

SDS Sections Revised:
Revision 01: Sections 1 to 16 contain revisions to comply with 29 CFR 1910.1200(g) and Appendix D**.**

GLOSSARY:

SDS	Safety Data Sheet
NA	Not Applicable
CAS Number	Chemical Abstract Service Registry Number
NTP	National Toxicology Program
NIOSH	National Institute for Occupational Safety and Health
DOT	Department of Transportation
IMDG	International Maritime Dangerous Goods Code
ICAO	International Civil Aviation Organization
IATA	International Air Transport Association
IMO	International Maritime Organization
TSCA	Toxic Substances Control Act
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
SARA	Superfund Amendments and Reauthorization Act
OSHA	Occupational Safety and Health Administration

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