SAFETY DATA SHEETS

This SDS packet was issued with item:

078948693

N/A

SAFETY DATA SHEET

According to Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Eight Revised Edition UNITED NATIONS New York and Geneva, 2021

Prazosin Hydrochloride Capsules USP (1 mg, 2mg, 5mg)

1. IDENTIFICATION

GHS Product identifier: Prazosin Hydrochloride Capsules USP
Product code:#
Chemical Description:1-(4-Amino-6,7-dimethoxy-2-quinazolinyl)-4-(2-furoyl)piperazine monohydrochloride
Other means of identification:
Recommended use of the chemical: Treatment of high blood pressure.

Restrictions on use: The product should be used only for the above mentioned uses and may not be used for any other purpose than stated above.

Manufactured by:
Mankind Pharma Ltd.,
Unit III, Opp. Dental College, Rampur Ghat,
Teh. -Paonta Sahib (HP-173025), India.
CIN No.: U74899DL1991PLC044843

Emergency phone number: +91 1704227600

2. HAZARDS IDENTIFICATION

Classification
Globally Harmonized System, UN (GHS)

Classification	Category	Exposure Route
Skin Irritation	3	
Reproductive toxicity	2	
Aquatic toxicity	Chronic 4	-

Labeling
Globally Harmonized System, UN (GHS)

Classification	
Signal Word	**Warning**
Hazard Statements:	H315: Causes skin irritation H361 Suspected of damaging fertility or the unborn child . H413: May cause long lasting harmful effects to aquatic life [Hazardous to the aquatic environment, long-term hazard

Precautionary Statements:	P264: Wash hands thoroughly after handling. P272: Contaminated work clothing should not be allowed out of the Workplace. P273: Avoid release to the environment. P280: Wear protective gloves/protective clothing/eye protection/face Protection. P284: Wear respiratory protection. P305 + P351 + P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P332+P313 If skin irritation occurs: Get medical advice/attention. P337+P313: If eye irritation persists: Get medical advice/attention. P362: Take off contaminated clothing. P405: Store locked up
Other hazards	None.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical nature: Mixture containing Alosetron HCl

Hazardous ingredients	CAS	Content
Prazosin Hydrochloride	19237-84-4	0.81 – 2.03%
Microcrystalline cellulose	9004-34-6	Up to 90%
Lactose monohydrate	64044-51-5	~ 25%
Sodium lauryl sulphate	151-21-3	< 1%
Colloidal silicondioxide	7631-86-9	<1%
Magnesium Sterate	557-04-0	< 1%

4. FIRST-AID MEASURES

Inhalation

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

Skin contact

Wash off with soap and plenty of water. Take victim immediately to hospital. Consult a physician.

Eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician

Ingestion

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician

5. FIRE-FIGHTING MEASURES

Fire extinguishing agents

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Fire/explosion hazard

No data available

Specific hazards arising from the capsules

None

Personal protection

Self-contained breathing apparatus. Fire-fighters must wear self-contained breathing apparatus for firefighting if necessary

Special exposure hazards

Do not release chemically contaminated water into drains, soil or surface water. Dispose of contaminated water and soil according to local regulations.

6. ACCIDENTAL RELEASE MEASURES

Personal protection

Goggles, gloves, protective clothing, respiratory protection.
Remove ignition sources and provide sufficient ventilation.

Environmental precautions

Prevent contamination of soil, drains and surface waters.

Spillage procedure

Take up mechanically and collect in suitable container (adequately labelled) for disposal.

7. HANDLING AND STORAGE

Handling

Occupational hygiene

Avoid ingestion, inhalation, skin and eye contact. Handle in accordance with good industrial hygiene practice and any legal requirements.

Conditions for safe storage

Ensure good local exhaust ventilation.
Keep away from heat/sparks/open flames/hot surfaces – No smoking.

Storage facilities

Storage tightly sealed in places with temperature between 20 °C to 25 °C (68 °F to 77 °F) [See USP Controlled Room Temperature]

Segregation

Store locked up.

Storage conditions

Keep containers closed.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Exposure limit values

Components with occupational exposure limits

CAS No	Name	TWA	STEL	Source
19237-84-4	Prazosin HCl	20 µg/m^3	-	Pfizer OEL TWA-8hr
557-04-0	Magnesium stearate	10 mg/m^3 (eye, skin, & URT irr)		ACGIH
9004-34-6	Cellulose	10 mg/m^3 (skin)		ACGIH

Occupational exposure controls

Appropriate engineering controls

Maintain air concentrations below occupational exposure standards. Prevent dust formation.

General Personal Protection

Goggles, gloves, protective clothing.

Respiratory protection

If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

Hand protection

Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations

Eye protection

Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin and body protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Solid
Form: Capsules
Colour: White opaque (1mg), Pink (2mg). Blue opaque (5mg)
Odour: N.A.
pH: Not applicable
Melting point: Not applicable
Boiling point: Not applicable
Flash point: Not applicable
Flammability (solid): Not available
Vapour pressure: Not applicable
Auto-ignition temperature: Not available
Decomposition temperature: Not available
Density: Not available
Solubility in water: Sparingly soluble
Solubility in solvents: Practically insoluble

n-Octanol/Water Partition Coefficient: Not available
Viscosity: Not applicable
Oxidizing properties: Not available
Explosivity: Stable under ordinary conditions

10. STABILITY AND REACTIVITY

Conditions to avoid
Avoid moisture
Materials to avoid
As a precautionary measure, keep away from strong oxidizers
Hazardous decomposition products
None under normal storage conditions

11. TOXICOLOGICAL INFORMATION

Acute toxicity
Prazosin HCl active ingredient has been tested for acute toxicity.

Prazosin HCl

LD_{50} Oral - Rat - 1,950 mg/kg

100% Prazosin is classified in category 4 for acute toxicity.

Lactose monohydrate

LD_{50} >10000 mg/kg

Microcrystalline cellulose
LD_{50} orally in Rabbit: > 5000 mg/kg LD_{50} dermal Rabbit > 2000 mg/kg

SLS
LD_{50} - 1288 mg/kg (category 4)

Colloidal silicondioxide
LD_{50}/oral/rat = 7900 mg/kg

Magnesium stearate
LD_{50} >10000 mg/kg (rat)

Based on toxicity data of Prazosin HCl and its excipients, Prazosin Capsules with <1% Prazosin HCl cannot be classified for acute toxicity.

Primary Irritation

Skin:
Prazozin HCl - GHS classification category 2
SLS - GHS classification category 2.
Magnesium stearate - GHS classification category 2.

Sum of ingredients categorised as skin category 2 are ≥ 1% but < 10%.

Based on data, mixture may be categorised as category 3.

Eye Irritation

Prazosin HCl is classified in category 2A.
SLS - GHS classification category 2 for skin irritation and category 1 for serious eye damage.
Magnesium stearate - GHS classification category 2.

GHS Classification is not applicable for the mixture.

Note:

Based on the 'Decision logic 3.3.2 for serious eye damage/irritation" of GHS classification, mixture is unlikely to fall under category 2 since the concentration of SLS and Magnesium stearate together is <10%.

Although SLS is classified for serious eye damage, it may be <1% in this capsule and hence not classified. If it is >1%, we may classify as category 1 the mixture for eye damage.

Respiratory or Skin sensitization -
Respiratory: Data not available.
GHS Classification is not possible.

CMR consideration:

Germ cell mutagenicity:
Data not available
GHS Classification is not possible.

Carcinogenicity

Not classifiable as human carcinogen.

No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity

Prazosin HCl classified as category 2.

Mixture is classified as category 2 since it contains ≥ 0.1% of category 2 active ingredient.

Specific target organ toxicity single exposure

Prazosin HCl classified as category 3. **Prazosin Capsules are not classifiable because of the low concentration of active ingredient.**

Specific target organ toxicity repeated exposure: Prazosin HCl classified as category 2. **Prazosin Capsules are not classifiable because of the low concentration of active ingredient.**

Data not available

Due to lack of data the GHS classification is not possible.

Aspiration hazard: Data not available.
GHS Classification is not possible.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Chronic toxicity: SLS and Magnesium stearate classified as chronic 3 and chronic 4 respectively. Based on the GHS classification for environmental hazards, the mixture has been classified as chronic 4.

Persistence and degradability
Data not available.

Behaviour in treatment plants
Data not available. GHS Classification is not possible.

Additional information
Do not discharge product uncontrolled into the environment.

13. DISPOSAL CONSIDERATIONS

Product disposal

Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Contaminated packaging

Contaminated, empty containers must be disposed of as chemical waste.

14. TRANSPORT INFORMATION

DOT
Not regulated as dangerous goods.
IATA
Not regulated as dangerous goods.
IMDG
Not regulated as dangerous goods.

15. REGULATORY INFORMATION

CLASSIFICATION AND LABELLING

Compliance with following regulations:

- Globally Harmonized System of Classification and Labelling of Chemicals (GHS), UNECE 2021 as amended
- UN Recommendations on the Transport of Dangerous Goods, UNECE 2009

16. OTHER INFORMATION

Recommended restrictions on use

This product should be stored, handled and used in accordance with good industrial hygiene practices and in conformity with any legal regulation. The information contained herein is based on the present state of our knowledge and is intended to describe our products from the point of view of safety requirements. It should not therefore be construed as guaranteeing specific properties.

MSDS Changes

Prepared on 20/12/22