



MATERIAL SAFETY DATA SHEET

Revision date: 02-Jan-2007

Version: 2.3

Page 1 of 5

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Pfizer Inc
Pfizer Pharmaceuticals Group
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Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Minipress (Prazosin hydrochloride) capsules - 1, 2, and 5 mg

Trade Name: MINIPRESS
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as antihypertensive

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Prazosin hydrochloride	19237-84-4	242-903-4	<1
Magnesium stearate/sodium lauryl sulfate blend	MIXTURE	Not listed	*
Corn Starch	9005-25-8	232-679-6	*

Ingredient	CAS Number	EU EINECS List	%
Confectioner's sugar	MIXTURE	Not listed	*
Purified water	7732-18-5	231-791-2	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: White capsules - 1 mg Pink and white capsules - 2 mg Blue and white capsules - 5 mg
Signal Word: WARNING

Statement of Hazard: Antihypertensive drug: has blood pressure-lowering properties

Additional Hazard Information:

Short Term: Not acutely toxic (based on animal data) .

Long Term: Animal studies have shown a potential to cause adverse effects on the fetus.

Known Clinical Effects: Ingestion of this material may cause effects similar to those seen in clinical use including hypotension (low blood pressure), dizziness, headache and drowsiness.

EU Indication of danger: Not classified

MATERIAL SAFETY DATA SHEET

Material Name: Minipress (Prazosin hydrochloride) capsules -
1, 2, and 5 mg

Page 2 of 5

Revision date: 02-Jan-2007

Version: 2.3

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

4. FIRST AID MEASURES

Eye Contact: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Remove clothing and wash affected skin with soap and water. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.

Ingestion: Get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Get medical attention immediately.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride and other chlorine-containing compounds.

Fire Fighting Procedures: Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear.

Fire / Explosion Hazards: Not available

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Minimize dust generation and accumulation. Use only in a well-ventilated area.

Storage Conditions: Keep container tightly closed when not in use. Store out of direct sunlight in a well ventilated area at room temperature.

MATERIAL SAFETY DATA SHEET

Material Name: Minipress (Prazosin hydrochloride) capsules -
1, 2, and 5 mg
Revision date: 02-Jan-2007

Page 3 of 5

Version: 2.3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Prazosin hydrochloride

Pfizer OEL TWA-8 Hr: 0.02 mg/m³

Corn Starch

OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
= 5 mg/m³ TWA

ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA

Australia TWA = 10 mg/m³ TWA

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

Analytical Method: Analytical method available for Prazosin hydrochloride. Contact Pfizer Inc for further information.

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Good general ventilation should be sufficient to control airborne levels.

Personal Protective Equipment:

Hands: Not required for the normal use of this product. Wear protective gloves when working with large quantities.

Eyes: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

Skin: Not required for the normal use of this product. Wear protective clothing when working with large quantities.

Respiratory protection: Not required for the normal use of this product. 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.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Capsule	Color:	White, white/pink, and white/blue
Odor:	Odorless	Molecular Formula:	Mixture
Molecular Weight:	Mixture		

10. STABILITY AND REACTIVITY

Stability: Stable
Conditions to Avoid: Light, moisture, and heat
Incompatible Materials: Strong oxidizers

Hazardous Decomposition Products: No data available

Polymerization: Will not occur

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the active ingredient.

Acute Toxicity: (Species, Route, End Point, Dose)

MATERIAL SAFETY DATA SHEET

Material Name: Minipress (Prazosin hydrochloride) capsules -
1, 2, and 5 mg

Page 4 of 5

Revision date: 02-Jan-2007

Version: 2.3

Prazosin hydrochloride

Mouse (M) Oral LD50 > 5000 mg/kg

Rat (M) Oral LD50 > 2000 mg/kg

Acute Toxicity Comments:

A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Subchronic Effects

In a one-month oral study in dogs at doses ranging from 2 to 40 mg/kg/day, drug-related pharmacologic responses were apparent at all doses. However, toxicity was observed only at the high dose level of 40 mg/kg/day with animals exhibiting ocular inflammation, vomiting, ataxia, diarrhea, anorexia, and histologic evidence of liver toxicity. In a one-month oral toxicity study in rats at doses up to 160 mg/kg/day, no evidence of toxicity was seen among treated animals.

Chronic Toxicity

Chronic toxicity was evaluated in rats and dogs at oral dose levels ranging from 5 to 150 mg/kg/day for 18 months and 2 to 25 mg/kg/day for one year, respectively. Testicular atrophy and hepatocellular degeneration were noted in rats at dose levels of 25 mg/kg or greater. In dogs, splenic enlargement was seen at all doses and testicular atrophy was noted at the highest dose. The splenic enlargement seen in dogs was caused by congestion and is considered to be the result of peripheral vasodilation (a secondary pharmacologic effect) rather than of toxicity. The testicular effects were not confirmed in a second one-year dog study using a single dose level of 25 mg/kg/day.

Chronic Effects/Carcinogenicity

No evidence of carcinogenic potential was seen in an 18-month oral rat study at dose levels up to 75 mg/kg/day.

Reproductive Effects

Fertility and reproductive performance were evaluated in rats at doses up to 75 mg/kg/day. Decreased fertility was seen at the high-dose, but no adverse effects were noted at the mid-dose (25 mg/kg/day). Decreased body weight gain was seen among the rat pups in Phase II of the study at the lowest dose of 5 mg/kg/day. A peri- and postnatal study was conducted in rats at doses up to 75 mg/kg/day. This study revealed decreased survival rate in rat pups and decreased litter size in animals receiving the high-dose.

Teratogenicity

No evidence of teratologic potential was observed in rats or rabbits at dose levels up to 75 mg/kg/day or in monkeys at dose levels up to 4 mg/kg/day. Liver Testes

Mutagenicity

No evidence of mutagenic potential in in vivo genetic toxicity studies.

Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

At increase risk from exposure:

Individuals with a known sensitivity to quinazolines (e.g. prazosin, terazosin) and impaired liver function may be more susceptible to toxicity upon overexposure.

12. ECOLOGICAL INFORMATION

Environmental Overview:

The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures:

Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

MATERIAL SAFETY DATA SHEET

Material Name: Minipress (Prazosin hydrochloride) capsules -
1, 2, and 5 mg

Page 5 of 5

Revision date: 02-Jan-2007

Version: 2.3

15. REGULATORY INFORMATION

EU Indication of danger: Not classified

OSHA Label:

WARNING

Antihypertensive drug: has blood pressure-lowering properties

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A



Prazosin hydrochloride

Australia (AICS):	Present
EU EINECS List	242-903-4

Corn Starch

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-679-6

Purified water

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-791-2

16. OTHER INFORMATION

Reasons for Revision: Updated Section 3 - Hazard Identification. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without a warranty of any kind, expressed or implied.

End of Safety Data Sheet