CLONIDINE HYDROCHLORIDE

Catalog Number: 1140407
Package Size: 200 mg
Revision Date: April 5, 2004

SECTION 1 - IDENTIFICATION

Common Name: Clonidine Hydrochloride
Synonym: n/f
Chemical Name: Benzenamine, 2,6-dichloro-N-2-imidazolidinylidene-, monohydrochloride
CAS Number: 4205-91-8
RTECS Number: NJ2490000
Chemical Family: Imidazoline
Therapeutic Category: Antihypertensive

SECTION 2 - INGREDIENT INFORMATION

<table>
<thead>
<tr>
<th>Principle Components</th>
<th>Percent</th>
<th>Exposure Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clonidine Hydrochloride</td>
<td>Pure Material</td>
<td>n/f</td>
</tr>
</tbody>
</table>

SECTION 3 - HEALTH HAZARD INFORMATION

Usual Adult Dose: The usual oral adult dose of clonidine hydrochloride is 100 to 600 micrograms (0.1 to 0.6 mg) in divided doses, not to exceed 2.4 mg per day. Clonidine hydrochloride is also applied topically to the skin, in doses of 100 micrograms (0.1 mg) per day.

Adverse Effects: Adverse effects may include mental depression; swelling of feet and lower legs; constipation; dizziness; drowsiness; dry mouth; unusual tiredness or weakness; loss of appetite; decreased sexual ability; dry, itchy or burning eyes; lightheadedness or fainting; nausea; vomiting; and nervousness. Possible allergic reaction to material if inhaled, ingested or in contact with skin.
CLONIDINE HYDROCHLORIDE

Overdose Effects: Symptoms of overdose may include dizziness or fainting, difficulty breathing, slowed heartbeat, pinpoint pupils, feeling cold, and extreme tiredness or weakness.

Acute: Possible eye, skin, gastrointestinal and/or respiratory tract irritation.

Chronic: Possible hypersensitization and tolerance.

Inhalation: May cause irritation. Avoid inhalation. Remove to fresh air.

Eye: May cause irritation. Flush with copious quantities of water.

Skin: May cause irritation, contact dermatitis, and darkening of skin. Avoid contact. Flush with copious quantities of water. This material is slowly absorbed through the skin.

Ingestion: May cause irritation, bitter taste, and toxicity. Avoid ingestion. Flush out mouth with water. This material is well absorbed from the gastrointestinal tract. Onset of action is 30 to 60 minutes; duration is 8 hours.

Medical Conditions Aggravated by Exposure: Hypersensitivity to material.

Cross Sensitivity: Persons sensitive to ophthalmic apraclonidine may be sensitive to this material also.

Pregnancy Comments: Adequate and well-controlled pregnancy studies in humans have not been done. Some studies in animals have shown clonidine to cause embryo death following both low and high doses; however, other studies in animals have not shown clonidine to cause adverse effects.

Pregnancy Category: C

SECTION 4 - FIRST AID MEASURES

General: Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.

Overdose Treatment: Treatment for clonidine overdose should be symptomatic and supportive and may include the following:
1. Do NOT induce vomiting. Gastric lavage may be useful following recent and/or large ingestion. Administration of activated charcoal and/or a cathartic may be beneficial.
2. For bradycardia - Use atropine sulfate.
3. For hypertension - Administer intravenous furosemide, diazoxide, phentolamine, or nitroprusside.
4. For hypotension - Consider intravenous fluids or vasopressor agents; administer a dopamine infusion.
5. Naloxone may be useful for management of respiratory depression, hypotension, or coma; monitor blood pressure for paradoxical hypertension.
6. If necessary, use a tolazoline infusion; however, this is not recommended due to inconsistent outcomes.
7. Dialysis is not likely to significantly enhance elimination. [USP DI 2004 and PDR 2004]

SECTION 5 - TOXICOLOGICAL INFORMATION

Oral Rat: LD50: 126 mg/kg
Oral Mouse: LD50: 135 mg/kg
Irritancy Data: n/f
Target Organ(s): Cardiovascular system and central nervous system.

Listed as a Carcinogen? NTP: No IARC: No OSHA: No

Other: No

SECTION 6 - FIREFIGHTING MEASURES

Flash Point: n/f Upper Flammable Limit: n/f
SECTION 7 - PHYSICAL HAZARDS

Conditions to Avoid: Avoid exposure to moisture.
Incompatibilities: Oxidizing agents
Decomposition Products: When heated to decomposition material emits toxic fumes of NOx and Cl-. Emits toxic fumes under fire conditions.

Stable? Yes  Hazardous Polymerization? No

SECTION 8 - HANDLING / SPILL / DISPOSAL MEASURES

Handling: As a general rule, when handling USP Reference Standards avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Wash thoroughly after handling.
Storage: Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.
Spill Response: Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.
Disposal: Dispose of waste in accordance with all applicable Federal, State and local laws.

SECTION 9 - EXPOSURE CONTROLS / PERSONAL PROTECTION

Respiratory Protection: Use a NIOSH approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.
Ventilation: Recommended.
Gloves: Rubber
Eye Protection: Safety Goggles
Protective Clothing: Protect exposed skin.

SECTION 10 - PHYSICAL AND CHEMICAL PROPERTIES

NOTE: The data reported below is general information, and is not specific to the USP Reference Standard Lot provided!

Appearance and Odor: A fine, white crystalline powder; odorless.
Melting Point: 305 - 312°C
Solubility in Water: Soluble
Boiling Point: n/f
Specific Gravity: n/f
Vapor Pressure: n/f
Vapor Density: n/f
Evaporation Rate: n/f
Reactivity in Water: n/f
% Volatile by Volume: n/f