PHENYLEPHRINE HYDROCHLORIDE INJECTION, USP

Section One: Identification

Common Brand Name: Phenylephrine Hydrochloride Injection, USP
Chemical Name: (±)-m-Hydroxy-α-[(methylamino)methyl]benzyl alcohol hydrochloride
Therapeutic Category: Vasoconstrictor/pressor drug
Controlled Substance: no

Section Two: Ingredient Information

<table>
<thead>
<tr>
<th>Components</th>
<th>Percent</th>
<th>Exposure Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>phenylephrine hydrochloride</td>
<td>1</td>
<td>NF¹</td>
</tr>
<tr>
<td>sodium chloride</td>
<td>0.35</td>
<td>NF</td>
</tr>
<tr>
<td>sodium citrate dihydrate</td>
<td>0.4</td>
<td>NF</td>
</tr>
<tr>
<td>sodium metabisulfite</td>
<td>0.2</td>
<td>5 mg/m³ TWA (ACGIH), 5 mg/m³ TWA (NIOSH)</td>
</tr>
<tr>
<td>citric acid</td>
<td>0.09</td>
<td>NA</td>
</tr>
<tr>
<td>water for injection</td>
<td>qs</td>
<td>pH</td>
</tr>
<tr>
<td>sodium hydroxide</td>
<td>to pH</td>
<td>2 mg/m³ ceiling (ACGIH), 10 mg/m³ (IDLH), 2 mg/m³ TWA (OSHA)</td>
</tr>
</tbody>
</table>

Section Three: Health Hazard Information

Usual Adult Dosage: Subcutaneously or Intramuscularly: Usual dose, from 2 mg to 5 mg. Range, from 1 mg to 10 mg. Initial dose should not exceed 5 mg.
Intravenously: Usual dose, 0.2 mg. Range, from 0.1 mg to 0.5 mg. Initial dose should not exceed 0.5 mg.

See package insert for other routes of administration.

Adverse Effects: If used in conjunction with oxytocic drugs, the pressor effect of sympathomimetic pressor amines is potentiated. The obstetrician should be warned that some oxytocic drugs may cause severe persistent hypertension and that even a rupture of a cerebral blood vessel may occur during the postpartum period.

Headache, nausea or vomiting, chest pain, change in heart rate, difficulty breathing, nervousness, reflex bradycardia, excitability, and restlessness.

Overdose Effects: Symptoms of overdose may include irregular heartbeat, severe increase in blood pressure, a sensation of fullness in the head, and tingling of the extremities.

Acute: May cause adverse central nervous system and cardiovascular reactions. Contains sodium metabisulfite, may cause allergic type reactions with anaphylactic symptoms/asthmatic episodes in susceptible people.

Chronic: Possible hypersensitization.

Inhalation: Causes irritation and is absorbed by this route. Remove to fresh air. Obtain medical attention.

Eyes: Causes irritation and is absorbed by this route. Flush with copious quantities of water for 15 minutes. Obtain medical attention.

¹ Not Found.
Skin: Causes irritation and is absorbed by this route. Flush with copious quantities of water for 15 minutes. Obtain medical attention.

Ingestion: May cause irritation, bitter taste, and toxicity. Flush out of mouth with water. This material is irregularly absorbed from the gastrointestinal tract. Obtain medical attention.

Medical Conditions Aggravated by Exposure: Should not be used in patients with severe hypertension or ventricular tachycardia. Should be employed only with extreme caution in elderly patients or in patients with hyperthyroidism, bradycardia, partial heart block, myocardial disease, or severe arteriosclerosis.

Cross Sensitivity: Contraindicated in patients who are hypersensitive to Phenylephrine, MAOI or to any of the components of the drug product. Use with great caution during halothane anesthesia.

Drug Abuse and Dependence: None known.

Pregnancy Comments: Animal reproduction studies have not been conducted with Phenylephrine Hydrochloride. It is also not known whether Phenylephrine Hydrochloride can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Phenylephrine Hydrochloride should be given to a pregnant woman only if clearly needed.

Pregnancy Category: C

Section Four: 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: Most overdoses require only patient observation because phenylephrine has a very short duration of action. Should an excessive elevation of blood pressure occur, it may be immediately relieved by a α-adrenergic blocking agent (e.g., Phentolamine).

Section Five: Toxicological Information

Oral Rat: LD50: 350 mg/kg
Oral Mouse: LD50: 120 mg/kg
Irritancy Data: NF
Target Organ(s): NF
Listed as a Carcinogen? NTP -no IARC- no OSHA- no Other- no

Section Six: Firefighting Measures

Flash Point: NF
Auto-Ignition Temperature: NF
Extinguisher Media: Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

Fire and Explosion Hazards: This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

Firefighting Procedures: As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and clothing. Use water in flooding amounts.

Section Seven: Physical Hazards

Conditions to Avoid: Avoid exposure to light.

Incompatibilities: Strong oxidizing agents, acids, acid chlorides, and acid anhydrides.

Decomposition Products: When heated to decomposition, material emits toxic fumes of NOₓ. Emits toxic fumes under fire conditions.
Stable? Yes
Hazardous Polymerization? No

Section Eight: Handling/ Spill/ Disposal Measures
Handling: Avoid all contact and inhalation of vapors associated with this material. Wash thoroughly after handling.
Storage: Store at controlled room temperature 15º-30º (59º-86ºF). Protect from light.
Spill Response: Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage with a high efficiency vacuum cleaner. Place spillage in appropriately labeled container for disposal. Wash spill site.
Disposal: Dispose of waste in accordance with all applicable Federal, State and local laws.

Section Nine: 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 glasses
Protective Clothing: Protect exposed skin.

Section Ten: Physical and Chemical Properties
Appearance and Odor: Clear, colorless solution.
Melting Point: NF
Solubility: water
Boiling Point: NF
Specific Gravity: NF
Vapor Pressure: NF
Vapor Density: NF
Evaporation Rate: NF
Reactivity in Water: NF
% Volatile by Volume: NF

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