PRESCRIBING INFORMATION

Phenylephrine Hydrochloride Injection USP

10 mg / mL

For subcutaneous, intramuscular or intravenous injection only

Vasopressor

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WARNING: PHYSICIANS SHOULD COMPLETELY FAMILIARIZE THEMSELVES WITH THE COMPLETE CONTENTS OF THIS PRESCRIBING INFORMATION BEFORE PRESCRIBING THIS DRUG.

DESCRIPTION

Phenylephrine Hydrochloride Injection USP is a vasoconstrictor and pressor drug chemically related to epinephrine and ephedrine.

PHARMACOLOGY

When applied topically or infiltrated into the tissues, phenylephrine produces vasoconstriction that lasts longer than that of epinephrine and ephedrine. Its action on the heart contrasts sharply with that of epinephrine and ephedrine, in that it slows the heart rate and increases the stroke output, inducing no disturbance in the rhythm of the pulse.

In therapeutic doses, it produces little if any stimulation of either the spinal cord or cerebrum. A singular advantage of this drug is the fact that repeated injections produce comparable effects.

INDICATIONS

For the maintenance of blood pressure during spinal and inhalation anesthesia, and also for overcoming peripheral vascular failure in shock and shock-like states, drug-induced hypotension, or hypersensitivity. Employed to overcome paroxysmal supraventricular tachycardia, to prolong spinal anesthesia and as a vasoconstrictor in regional anesthesia.

PRECAUTIONS

May be contraindicated in patients with hypertension or ventricular tachycardia or in patients who are hypersensitive to the drug.

Should be used with extreme caution in elderly patients or those with hyperthyroidism, bradycardia, partial heart block, myocardial disease, or severe arteriosclerosis.

Vasopressors may cause serious cardiac arrhythmias during halothane anesthesia and therefore should be used only with great caution or not at all.

Contains sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in non-asthmatic people.

Oxytocics: In obstetrics, if vasopressor drugs are either used to correct hypotension or added to the local anesthetic solution, 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.

MAO Inhibitors: The pressor effects of sympathomimetic pressor amines are markedly potentiated in patients receiving a monoamine oxidase (MAO) inhibitor. Therefore, when initiating pressor therapy in these patients, the initial dosage should be small and used with due caution.

The pressor response of adrenergic agents may also be potentiated by tricyclic antidepressants.

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

Lactation: It is not known whether this drug is excreted in human milk. Because many are excreted in human milk, caution should be exercised when phenylephrine is administered to a nursing woman.

ADVERSE EFFECTS

Headache, reflex bradycardia, excitability, restlessness, and rarely arrhythmia.

OVERDOSAGE

For management of a suspected drug overdose, contact your regional poison control centre.

Symptoms: Overdosage may induce ventricular extrasystoles and short paroxysms of ventricular tachycardia, sensations of fullness in the head, and tingling of the extremities.
Treatment: An excessive elevation of blood pressure may be immediately relieved by an α-adrenergic blocking agent.

DOSAGE AND ADMINISTRATION

Phenylephrine Hydrochloride Injection USP is generally injected subcutaneously, intramuscularly, slowly intravenously, or in dilute solution as a continuous intravenous infusion. In patients with paroxysmal supraventricular tachycardia and, if indicated, in case of emergency, phenylephrine is administered directly intravenously. The dose should be adjusted according to the pressor response.

Dosage Calculations

Dose required	Use Phenylephrine Hydrochloride Injection USP 10 mg / mL (1%)
10 mg	1 mL
5 mg	0.5 mL
1 mg	0.1 mL

For convenience in intermittent intravenous administration, dilute 1 mL of Phenylephrine Hydrochloride Injection USP 10 mg / mL with 9 mL of Sterile water for injection USP.

Dose required	Use diluted Phenylephrine Hydrochloride Injection USP 1 mg / mL (0.1 %)
0.1 mg	0.1 mL
0.2 mg	0.2 mL
0.5 mg	0.5 mL

Mild or Moderate Hypotension:
Subcutaneous or Intramuscular: Usual dose: from 2 to 5 mg. Range: from 1 to 10 mg.
The initial dose should not exceed 5 mg.

Intravenous: Usual dose: 0.2 mg. Range: from 0.1 to 0.5 mg.
The initial dose should not exceed 0.5 mg.

Injections should not be repeated more often than every 10 to 15 minutes. A 5 mg intramuscular dose should raise blood pressure for 1 to 2 hours. A 0.5 mg intravenous dose should elevate the pressure for about 15 minutes.

Severe Hypotension and Shock:
Blood volume depletion should always be corrected as fully as possible before any vasopressor is administered. When, as an emergency measure, intra-aortic pressures must be maintained to prevent cerebral or coronary artery ischemia, phenylephrine can be administered before and concurrently with blood volume replacement.

Higher initial and maintenance doses of phenylephrine are required in patients with persistent or untreated severe hypotension or shock. Hypotension produced by powerful peripheral adrenergic blocking agents, chlorpromazine, or pheochromocytomectomy may also require more intensive therapy.

Continuous infusion:
Add 10 mg of the drug (1 mL of 1% solution) to 500 mL of Dextrose Injection USP or Sodium Chloride Injection USP (providing a 1:50 000 solution). To raise the blood pressure rapidly, start

the infusion at about 100 to 180 mcg / minute (based on 20 drops / mL, this would be 100 to 180 drops / minute). When the blood pressure is stabilized (at a low normal level for the individual), a maintenance rate of 40 to 60 mcg / minute usually suffices (based on 20 drops / mL, this would be 40 to 60 drops / minute). If the drop size of the infusion system varies from 20 drops / mL, the dose must be adjusted accordingly. If a prompt initial pressor response is not obtained, additional increments of phenylephrine (10 mg or more) are added to the infusion bottle. The rate of flow is then adjusted until the desired blood pressure level is obtained. (In some cases, a more potent vasopressor, such as norepinephrine, may be required). Hypertension should be avoided. The blood pressure should be checked frequently. Headache and / or bradycardia may indicate hypertension, Arrhythmias are rare.

Spinal Anesthesia – Hypotension:
Routine parenteral use of phenylephrine has been recommended by many investigators for the prophylaxis and treatment of hypotension during spinal anesthesia. It is best administered subcutaneously or intramuscularly 3 or 4 minutes before injection of the spinal anesthetic. The total requirement for high anesthetic levels is usually 3 mg and for lower levels, 2 mg. For hypotensive emergencies during spinal anesthesia, phenylephrine may be injected intravenously beginning with a dose of 0.2 mg. Any subsequent dose should not exceed the previous dose by more than 0.1 to 0.2 mg and should not be more than 0.5 mg. To combat hypotension during spinal anesthesia in children a dose of 0.5 to 1 mg / 11.3 kg of body weight, administered subcutaneously or intramuscularly, is recommended.

Prolongation of Spinal Anesthesia:
The addition of 2 to 5 mg of phenylephrine to the anesthetic solution increases the duration of motor block by as much as approximately 50% without any increase in the incidence of complications such as nausea, vomiting, or blood pressure disturbances.

Vasoconstrictor for Regional Analgesia:
Concentrations about 10 times those of epinephrine are recommended. The optimum strength is 1:20 000 (made by adding 1 mg of phenylephrine to every 20 mL of local anesthetic solution). Some pressor responses can be expected when 2 mg or more are injected.

Paroxysmal Supraventricular Tachycardia:
Rapid intravenous injection (within 20 to 30 seconds) is recommended; the initial dose should not exceed 0.5 mg and subsequent doses, which are determined by the initial blood pressure response, should not exceed the preceding dose by more than 0.1 to 0.2 mg and should never exceed 1 mg.

Drug-Induced Reactions:
Hypotension and occasionally severe shock may result from overdosage or idiosyncrasy following the administration of certain drugs, especially adrenergic and ganglionic blocking agents, rauwolfia and veratrum alkaloids and phenothiazine tranquillizers. Patients who receive a phenothiazine derivative as a preoperative medication are especially susceptible to these reactions. As an adjunct in the management of such episodes, phenylephrine is a suitable agent for restoring blood pressure.

SUPPLIED

Each mL of sterile solution contains: 10 mg of phenylephrine hydrochloride in water for injection.

Non-medicinal ingredients: Citric acid monohydrate 1 mg, sodium chloride 3.5 mg, sodium metabisulfite 2 mg, trisodium citrate dihydrate 4 mg, and water for injection.

The pH is adjusted between 3.5 and 5.5 with hydrochloric acid or sodium hydroxide.

Phenylephrine Hydrochloride Injection USP is available in 1 mL and 5 mL fill volumes. Cartons of 10 vials.

The air in vials has been displaced by nitrogen gas.

STORAGE

Store at 15-30°C. Protect from light.
Do not use product if solution shows haziness, particulate matter, discolouration, or leakage.
Phenylephrine Hydrochloride Injection USP will be kept in its original packaging (carton) when not in use.

SINGLE-USE VIAL

Discard unused portion.

SUPPORTING PRESCRIBING INFORMATION

1. Phenylephrine Hydrochloride Injection USP 1% (solution, 10 mg/mL), Prescribing Information, Omega Laboratories Ltd. (November 1999)
2. Phenylephrine Hydrochloride Injection USP (solution, 10 mg/mL) submission control 232497, Prescribing Information, SteriMax Inc. (August 31, 2020)

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

Note: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

If you want more information about Phenylephrine Hydrochloride Injection USP:

- Talk to your healthcare professional
- Find the full Prescribing Information that is prepared for healthcare professionals by visiting the Health Canada website: https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html; or by calling 1-866-399-9091.

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