**PRESCRIBING INFORMATION**

**PHENYLEPHRINE HYDROCHLORIDE INJECTION**

**500 mcg / 10 mL**
(50 mcg/mL)

Vasopressor
Intravenous (i.v.)

**PHYSICIANS SHOULD COMPLETELY FAMILIARIZE THEMSELVES WITH THE COMPLETE CONTENTS OF THIS LEAFLET BEFORE PRESCRIBING THIS DRUG.**

## DESCRIPTION

PHENYLEPHRINE HYDROCHLORIDE INJECTION 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. Phenylephrine is a post-synaptic alpha-receptor agonist with little effect on the beta receptors of the heart. Following its intravenous administration, increases in systolic and diastolic blood pressure, and total peripheral vascular resistance are observed rapidly, typically within minutes following i.v. bolus administration. As blood pressure increases, vagal activity also increases, resulting in reflex bradycardia.

## INDICATIONS

For the treatment of clinically important hypotensive states, including overcoming peripheral vascular failure (shock or shock-like states), maintenance of blood pressure in the setting of anesthesia, drug-induced hypotension, or hypersensitivity with circulatory compromise.

## CONTRAINDICATION

Contraindicated in patients with hypertension or ventricular tachycardia or in patients who are hypersensitive to the drug.

## PRECAUTIONS

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.

**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 a pregnant woman only if clearly needed.

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

## ADVERSE REACTIONS

Headache, reflex bradycardia, hypertension, excitability, restlessness and rarely arrhythmias.

## OVERDOSE

**Symptoms:** Overdosage may induce ventricular extra-systoles 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

The dose should be adjusted according to the pressor response.

I.V.: Usual dose: 200 mcg. Range: from 100 to 500 mcg. Initial dose should not exceed 500 mcg.

Injections should not be repeated more often than every 10 to 15 minutes. A 500 mcg i.v. dose should elevate the pressure for about 15 minutes.

Blood volume depletion should always be corrected as fully as possible before any vasopressor is administered.

## DOSAGE FORM, COMPOSITION AND PACKAGING

**Dosage form:**
PHENYLEPHRINE HYDROCHLORIDE INJECTION (50 mcg/mL) is a clear, colourless, pyrogen free, and sterile solution. Do not use product if mixture (solution) shows haziness, particulate matter, discolouration, or leakage.

**Packaging:**
PHENYLEPHRINE HYDROCHLORIDE INJECTION is supplied in a sterile 10 mL polypropylene pre-filled, ready-to-use syringe, packaged in a blister pack.

**Composition:**
Each 10 mL pre-filled syringe contains:
Phenylephrine hydrochloride 500 mcg in water for injection.
Non-medicinal Ingredients:
Sodium chloride 79 mg, citric acid monohydrate 10 mg and sodium citrate dihydrate 24.25 mg. The pH is adjusted to 5 with sodium hydroxide.

**Latex free stopper. Preservative free.**

## STORAGE AND STABILITY

Store syringe in blister pack in original package. Protect from light. Store between 15°C - 30°C.

## SINGLE USE PRE-FILLED SYRINGE

Discard unused portion.

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