

# PHENYLEPHRINE HYDROCHLORIDE- phenylephrine hydrochloride injection

## Assure Infusions, Inc

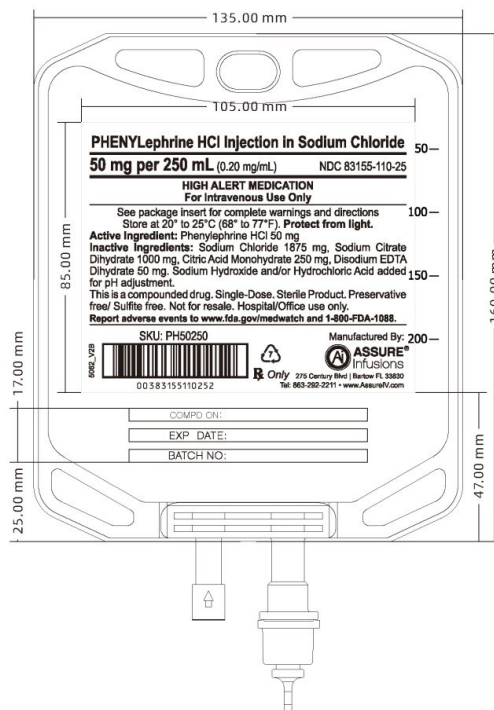
*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

### Phenylephrine Hydrochloride, 50mg in 250mL


### Storage and Handling Section

See package insert for complete warnings and directions.


Store at 20 to 25C (68 to 77F). Protect from light.



LABEL .PNG




### PHENYLEPHERINE HCL INJECTION IN SODIUM CHLORIDE



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For Human Use Only



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**HIGHLIGHTS OF PRESCRIBING INFORMATION:**  
These highlights do not include all the information needed to use Phenylephrine Hydrochloride as 0.75% Sodium Chloride Injection safely and effectively. See full prescribing information.

**FULL PRESCRIBING INFORMATION:**

**1. INDICATIONS AND USAGE**  
Phenylephrine Hydrochloride in 0.75% Sodium Chloride Injection is indicated for increasing blood pressure in adults with clinically important hypotension resulting primarily from vasodilation in the setting of anesthesia.

**2. DOSAGE AND ADMINISTRATION**  
2.1 General Administration Instructions  
During Phenylephrine Hydrochloride 10 mg in 250 mL (0.04mg/mL), 20 mg in 250 mL (0.08mg/mL), 40 mg in 250 mL (0.16mg/mL), and 50 mg in 250 mL (0.20mg/mL) in 0.75% Sodium Chloride Injection administration:  
• Correct intravascular volume depletion.

peripheral vascular disease.

**5.7 Renal Toxicity**  
Phenylephrine hydrochloride can increase the need for renal replacement therapy in patients with septic shock. Monitor renal function.

**6. ADVERSE REACTIONS:**  
The following adverse reactions associated with the use of phenylephrine hydrochloride were identified in the literature. Because these reactions are reported sporadically from a population of uncertain size, it is not always possible to estimate their frequency reliably or to establish a causal relationship to drug exposure.  
Cardiac: dizziness, bradycardia, AV block, ventricular

for Phenyloleprine Hydrochloride Injection.

### PHENYLEPBRINE HYDROCHLORIDE IN SODIUM CHLORIDE INJECTION, for intravenous use.

#### INDICATIONS AND USAGE:

Phenylephrine Hydrochloride in 0.75% Sodium Chloride Injection is an  $\alpha$ -1 adrenergic receptor agonist indicated for increasing blood pressure in adults with clinically important hypotension resulting primarily from vasodilation, in the setting of anesthesia (1).

#### DOSEAGE AND ADMINISTRATION:

Do NOT dilute prior to administration (2,11).

##### Dosing for Perioperative Hypotension

- Intravenous continuous infusion: 0.5 mcg/kg/minute to 1.4 mcg/kg/minute titrated to effect (2,22).

#### DOSEAGE FORMS AND STRENGTHS:

Injection:

- 10 mg in 250 mL (0.04mg/mL) of phenylephrine hydrochloride, 20 mg in 250 mL (0.08mg/mL) of phenylephrine hydrochloride, 40 mg in 250 mL (0.16mg/mL) of phenylephrine hydrochloride, 50 mg in 250 mL (0.20mg/mL) of phenylephrine hydrochloride in 0.75% Sodium Chloride, supplied in a ready-to-use, single-dose intravenous solution bag (3, 11, 16).

#### CONTRAINDICATIONS:

- Hypersensitivity to it or any of its components (4).

#### WARNINGS AND PRECAUTIONS:

- Severe bradycardia and decreased cardiac output (5,2).
- Extravasation: During intravenous administration may cause necrosis or sloughing of tissue (5,4).
- Concomitant use with cytotoxic drugs: pressor effect of sympathomimetic pressor amines is potentiated (5,5).

#### ADVERSE REACTIONS:

Most common adverse reactions: nausea and vomiting; headache; nervousness (6).

To report SUSPECTED ADVERSE REACTIONS, contact Assure Infusions, Inc., at 1-863-292-2211 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

#### Drug Interactions

- Agonistic effects with monoamine oxidase inhibitors (MAOI),  $\beta$ -adrenergic blocking agents,  $\alpha$ -2 adrenergic agonists, steroids, tricyclic antidepressants, norepinephrine transport inhibitors, ergot alkaloids, centrally acting sympatholytic agents and atropine sulfate (7,1).
- Antagonistic effects on and by a adrenergic blocking agents (7,2).

Created on: 02/17/2026

#### Clinical Considerations:

##### Disease-Associated Maternal and/or Embryofetal Risk

Unlabeled hypotension associated with spinal anesthesia for cesarean section is associated with an increase in maternal nausea and vomiting. A sustained decrease in uterine blood flow due to maternal hypotension may result in fetal bradycardia and acidosis.

##### Data

###### Human Data

Randomized controlled trials over several decades, which compared the use of phenylephrine injection to other similar agents in pregnant women during cesarean section, have not identified adverse maternal or infant outcomes. At randomized doses, phenylephrine does not appear to affect fetal heart rate or fetal heart variability to a significant degree.

There are no studies on the safety of phenylephrine injection exposure during the period of organogenesis, and therefore, it is not possible to draw any conclusions on the risk of birth defects following exposure to phenylephrine injection during pregnancy. In addition, there are no data on the risk of miscarriage following fetal exposure to phenylephrine injection.

###### Animal Data

No clear malformations or fetal toxicity were reported when nonmaternal pregnant rabbits were treated with phenylephrine via continuous intravenous infusion over 1 hour (0.8 mg/kg/day, approximately equivalent to a HDD based on body surface area) from Gestation Day 7 to 19. At this dose, which demonstrated no maternal toxicity, there was evidence of developmental delay, delayed ossification of sterna (8).

In a non-GLP dose range-finding study in nonmaternal pregnant rabbits, fetal lethality and cranial, paw, and limb malformations were noted following treatment with 1.2 mg/kg/day of phenylephrine via continuous intravenous infusion over 1 hour (2.3 times the HDD). This dose was clearly maternally toxic (increased mortality and significant body weight loss). An increase in the incidence of limb malformation (hyperostosis of the forelimb) associated with high fetal mortality was noted in a single litter at 0.6 mg/kg/day (1.2 times the HDD) in the absence of maternal toxicity.

No malformations or embryo-fetal toxicity were reported when nonmaternal pregnant rats were treated with up to 3 mg/kg/day phenylephrine via continuous intravenous infusion over 1 hour (2.9 times the HDD from Gestation Day 6 to 17). This dose was associated with some maternal toxicity (decreased food consumption and body weight).

Decreased pup weights were reported in a pre- and postnatal development toxicity study in which nonmaternal pregnant rats were administered phenylephrine via continuous intravenous infusion over 1 hour (0.3, 1.0, or 3.0 mg/kg/day, 0.29, 1, or 2.9 times the HDD from Gestation Day 6 through Lactation Day 21). No adverse effects on growth and development (learning and memory, sexual development, and fertility) were noted in the offspring of pregnant rats at any dose tested. Maternal toxicities (mortality late in gestation and during lactation period, decreased food consumption and body weight) occurred at 1 and 3 mg/kg/day of phenylephrine (equivalent to and 2.9 times the HDD, respectively).

###### 8.2 Lactation

###### Risk Summary

There are no data on the presence of Phenyloleprine Hydrochloride Injection or its metabolite in human or animal milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for phenylephrine hydrochloride injection and any potential adverse effects on the breastfed infant from phenylephrine hydrochloride injection or from the underlying maternal condition.

###### 8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

###### 8.6 Geriatric Use

Clinical studies of phenylephrine did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal,

or cardiac function, and of concomitant disease or other drug therapy.

#### 8.6 Hepatic Impairment

In patients with liver cirrhosis [Child Pugh Class A (n=3), Class B (n=5) and Class C (n=1)], dose-response data indicate decreased responsiveness to phenylephrine. Consider using larger doses than usual in hepatically impaired subjects.

#### 8.7 Renal Impairment

In patients with end stage renal disease (ESRD) undergoing hemodialysis, dose-response data indicates increased responsiveness to phenylephrine. Consider using lower doses of phenylephrine hydrochloride in ESRD patients.

#### 10. OVERDOSSAGE

Overdose of Phenyloleprine Hydrochloride Injection can cause a rapid rise in blood pressure. Symptoms of overdose include headache, vomiting, hypertension, tachycardia, and cardiac arrhythmias including ventricular arrhythmias and ventricular tachycardia, and may cause a sensation of fullness in the head and tingling of the extremities. Consider using an adrenergic antagonist.

#### 11. DESCRIPTION:

Phenylephrine Hydrochloride in 0.75% Sodium Chloride Injection, 10 mg/250 mL to 50 mg/250 mL, an agonist  $\alpha$ -1 adrenergic receptor, contains the active pharmaceutical ingredient phenylephrine in the form of hydrochloride salt. Phenyloleprine is a synthetic sympathomimetic agent in sterile form for parenteral injection. Phenyloleprine hydrochloride chemical name is (3-*n*-Hydroxy-*n*-(methylamino) ethyl) benzyl alcohol hydrochloride and has the following structural formula:



Phenylephrine hydrochloride is very soluble in water, freely soluble in ethanol, and insoluble in chloroform and ethyl ether. Phenyloleprine hydrochloride is sensitive to light.

Phenyloleprine Hydrochloride Injection, USP is a clear and colorless to pale yellow solution, essentially free of visible foreign matter. It is a ready-to-use solution intended for intravenous administration.

For 10mg/250mL: Each mL contains 0.04 mg (40 µg) of Phenyloleprine Hydrochloride and 7.5 mg of Sodium Chloride in Water for Injection.

For 20mg/250mL: Each mL contains 0.08 (80 µg) of Phenyloleprine Hydrochloride and 7.5 mg of Sodium Chloride in Water for Injection.

For 40mg/250mL: Each mL contains 0.16 mg (160 µg) of Phenyloleprine Hydrochloride and 7.5 mg of Sodium Chloride in Water for Injection.

For 50mg/250mL: Each mL contains 0.20 mg (200 µg) of Phenyloleprine Hydrochloride and 7.5 mg of Sodium Chloride in Water for Injection.

Hydrochloric acid is added as needed to adjust pH (pH range is 3.0 to 4.5 per USP monograph).

#### 12. CLINICAL PHARMACOLOGY:

##### 12.1 Mechanism of Action

Phenyloleprine hydrochloride is an  $\alpha$ -1 adrenergic receptor agonist.

Following parenteral administration of phenylephrine hydrochloride, increases in systolic blood pressure, diastolic blood pressure, mean arterial blood pressure, and total peripheral vascular resistance are observed. The onset of blood pressure increase following an intravenous bolus of phenylephrine hydrochloride administration is rapid and the effect may persist for up to 20 minutes. As mean arterial pressure increases following parenteral doses, splanchnic flow also increases, resulting in reflex bradycardia. Most vascular beds are constricted, including renal, splanchnic, and hepatic.

##### 12.2 Pharmacodynamics

Phenyloleprine is the active moiety. Metabolites are inactive at both the  $\alpha$ -1 and  $\alpha$ -2 adrenergic receptors. Following parenteral administration of phenylephrine hydrochloride, increases in systolic blood pressure, diastolic blood pressure, mean arterial blood pressure, and total peripheral vascular resistance are observed. The onset of blood pressure increase following an intravenous bolus of phenylephrine hydrochloride administration is rapid and the effect may persist for up to 20 minutes. As mean arterial pressure increases following parenteral doses, splanchnic flow also increases, resulting in reflex bradycardia. Most vascular beds are constricted, including renal, splanchnic, and hepatic.

##### 12.3 Pharmacokinetics

Following an intravenous infusion of phenylephrine hydrochloride, the effective half-life was approximately 5 minutes. The steady-state volume of distribution (V<sub>ss</sub>) exceeded the body volume by a factor of 5, suggesting a high distribution into certain organ

compartments, myocardial ischemia

*Gastrointestinal disorders:* Nausea, vomiting

*General disorders and administration site conditions:* Chest pain, extravasation

*Nervous system disorders:* Headache, nervousness, paraesthesia, tremor

*Psychiatric disorders:* Excitability

*Respiratory system disorders:* Dyspnea, rales

*Skin and subcutaneous tissue disorders:* Erythema, pallor, paresthesia, skin blanching, skin necrosis with extravasation

*Vascular disorders:* Hypertensive crisis

#### 7. Drug Interactions

##### 7.1 Agonists

The pressor effect of phenylephrine hydrochloride is increased in patients receiving:

- Monoamine oxidase inhibitors (MAOI), such as selegiline.
- Cytotoxic and cytotoxic drugs
- $\beta$ -adrenergic blockers
- $\alpha$ -2 adrenergic agonists, such as clonidine
- Steroids
- Tricyclic antidepressants
- Norepinephrine transport inhibitors, such as atomoxetine
- Ergot alkaloids, such as methylergometrine maleate
- Centrally acting sympatholytic agents, such as guanfacine or reserpine
- Atropine sulfate

##### 7.2 Antagonists

$\alpha$ -adrenergic blocking agents, including phentolamine (e.g., chlorpropranolol and alendazole block phenylephrine and are inactivated by phenylephrine).

#### 8. USE IN SPECIFIC POPULATION:

##### 8.1 Pregnancy

###### Risk Summary

Data from randomized controlled trials and meta-analyses with phenylephrine hydrochloride injection use in pregnant women during cesarean section have not established a drug-associated risk of major birth defects and miscarriage. These studies have not identified an adverse effect on maternal outcomes or infant APGAR scores (see Data). There are no data on the use of phenylephrine during the first or second trimester. In animal reproduction and development studies in nonrodent animals, evidence of fetal malformations was noted when phenylephrine was administered during organogenesis via a 1-hour infusion at 1.2 times a human daily dose (HDD) of 10 mg/60 kg/day. Decreased pup weights were noted in offspring of pregnant rats treated with 2.9 times the HDD.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

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compartments. The average total serum clearance (0.95 mL/min) was close to one-third of the cardiac output.

A mass balance study showed that phenylephrine is extensively metabolized by the liver with only 12% of the dose excreted unchanged in the urine. Metabolism by monoamine oxidase is the primary metabolic pathway resulting in the formation of the major metabolite *lm*-hydroxymandelic acid which accounts for 57% of the total administered dose.

#### 13. NON-CLINICAL TOXICOLOGY

##### 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

###### Carcinogenesis

Long-term animal studies that evaluated the carcinogenic potential of orally administered phenylephrine hydrochloride in F344/N rats and B6C3F1 mice were completed by the National Toxicology Program using the dietary route of administration. There was no evidence of carcinogenicity in mice administered approximately 270 mg/kg/day (131 times the human daily bolus injection) or 10 mg/kg/day based on body surface area) or rats administered approximately 50 mg/kg/day (42 times the HDD based on body surface area comparisons).

###### Mutagenesis

Phenyloleprine hydrochloride tested negative in the *in vitro* bacterial reverse mutation assay (S. typhimurium strains TA98, TA101, TA1538 and TA1537), the *in vitro* chromosome aberrations assay, the *in vitro* sister chromatid exchange assay, and the *in vivo* rat micronucleus assay. Positive results were reported in only one of two replicates of the *in vitro* mouse lymphoma assay.

###### Impairment of Fertility

No adverse effects on fertility or early embryonic development were noted when phenylephrine hydrochloride was administered at doses of 50 mg, 100 mg, or 200 mg/kg/day up to 0.2 times HDD (10 mg/kg/day based on body surface area) via single daily bolus injection for 28 days prior to mating (male rats) or for 14 days prior to mating (female rats) (7) to female rats.

#### 14. CLINICAL STUDIES

Increases in systolic and mean blood pressure following administration of phenylephrine were observed in 42 literature-based studies in the perioperative setting, including 26 studies where phenylephrine was used in low risk (ASA 1 and 2) pregnant women undergoing neuraxial anesthesia during cesarean delivery, 3 studies in non-obstetric surgery under neuraxial anesthesia, and 13 studies in patients undergoing surgery under general anesthesia. Data came from file reference ID # 6501090.

#### 16. HOW SUPPLIED, STORAGE AND HANDLING

Phenyloleprine Hydrochloride in 0.75% Sodium Chloride Injection is a clear, colorless solution supplied in a ready-to-use single dose 250 mL infusion bag as follows:

| Unit of Sale     | Strength  |
|------------------|-----------|
| NDC 83156-107-25 | 0.04mg/mL |
| NDC 83156-108-25 | 0.08mg/mL |
| NDC 83156-109-25 | 0.16mg/mL |
| NDC 83156-110-25 | 0.20mg/mL |

Store at 20°C to 25°C (68°F to 77°F), excursions permitted to 15°C to 20°C (59°F to 68°F) (See USP Controlled Room Temperature).

Discard any unused portion.

TAKE I OBTAIN LABEL TIME DIRECTIONS

Issued: February 2026

MANUFACTURED & DISTRIBUTED BY:

ASSURE INFUSIONS

276 Carlini Blvd, Barlow, FL 33830

863.292.2211 | info@AssureIV.com

www.AssureIV.com

Made in USA with Global Parts

For a copy of the Safety Data Sheet (SDS) or to report a safety concern call 863-292-2211

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# PHENYLEPBRINE HYDROCHLORIDE INJECTION

phenylephrine hydrochloride injection

**Product Information**

|                                |                         |                           |               |
|--------------------------------|-------------------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN PRESCRIPTION DRUG | <b>Item Code (Source)</b> | NDC:83155-110 |
| <b>Route of Administration</b> | INTRAVENOUS             |                           |               |

**Active Ingredient/Active Moiety**

| <b>Ingredient Name</b>   | <b>Basis of Strength</b>               | <b>Strength</b>    |
|--|--|--------------------|
| <b>PHENYLEPHRINE HYDROCHLORIDE, (+/-)-</b> (UNII: O2VT86KV7E)<br>(PHENYLEPHRINE HYDROCHLORIDE, (+/-)- - UNII:O2VT86KV7E) | PHENYLEPHRINE<br>HYDROCHLORIDE, (+/-)- | 50 mg<br>in 250 mL |

**Inactive Ingredients**

| <b>Ingredient Name</b>                                | <b>Strength</b>   |
|---|-------------------|
| <b>TRISODIUM CITRATE DIHYDRATE</b> (UNII: B22547B95K) | 1000 mg in 250 mL |
| <b>SODIUM CHLORIDE NA-22</b> (UNII: VMP9781061)       | 1875 mg in 250 mL |
| <b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)     | 250 mg in 250 mL  |

**Packaging**

| <b>#</b> | <b>Item Code</b> | <b>Package Description</b>                               | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|----------|------------------|--|-----------------------------|---------------------------|
| 1        | NDC:83155-110-25 | 250 mL in 1 CONTAINER; Type 0: Not a Combination Product | 03/20/2026                  |                           |

**Marketing Information**

| <b>Marketing Category</b> | <b>Application Number or Monograph Citation</b> | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|---------------------------|---|-----------------------------|---------------------------|
| unapproved drug<br>other  |   | 03/20/2026                  |                           |

**Labeler** - Assure Infusions, Inc (053016941)**Registrant** - Assure Infusions, Inc (053016941)**Establishment**

| <b>Name</b>           | <b>Address</b> | <b>ID/FEI</b> | <b>Business Operations</b> |
|-----------------------|----------------|---------------|----------------------------|
| Assure Infusions, Inc |                | 053016941     | manufacture(83155-110)     |

Revised: 3/2026

Assure Infusions, Inc