

PHENYLEPHRINE HYDROCHLORIDE- phenylephrine hydrochloride injection Civica, Inc.

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use PHENYLEPHRINE HYDROCHLORIDE safely and effectively. See full prescribing information for PHENYLEPHRINE HYDROCHLORIDE.

PHENYLEPHRINE HYDROCHLORIDE injection, for intravenous use
Initial U.S. Approval: 2012

RECENT MAJOR CHANGES

Dosage and Administration, Pharmacy Bulk Vials (2.6) 6/2019

INDICATIONS AND USAGE

Phenylephrine Hydrochloride is an alpha-1 adrenergic receptor agonist indicated for increasing blood pressure in adults with clinically important hypotension resulting primarily from vasodilation, in such settings as septic shock or anesthesia. (1)

DOSAGE AND ADMINISTRATION

Dilute before administration. (2.1)

Dosing for Perioperative Hypotension

- Intravenous bolus administration: 50 mcg to 250 mcg (2.4)
- Intravenous continuous infusion: 0.5 mcg/kg/minute to 1.4 mcg/kg/minute titrated to effect (2.4)

Dosing for Patients with Vasodilatory Shock

- Intravenous continuous infusion: 0.5 mcg/kg/minute to 6 mcg/kg/minute titrated to effect (2.5)

DOSAGE FORMS AND STRENGTHS

Injection: 10 mg/mL supplied as a:

- 1 mL single dose vial (3, 11, 16)
- 10 mL pharmacy bulk package vial (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 oxytocic drugs:* pressor effect of sympathomimetic pressor amines is potentiated (5.5)
- *Allergic-type reactions:* Sulfite (5.6)

ADVERSE REACTIONS

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

To report SUSPECTED ADVERSE REACTIONS, contact Hikma Pharmaceuticals USA Inc. at 1-877-845-0689 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- Agonistic effects with monoamine oxidase inhibitors (MAOI), β -adrenergic blocking agents, α -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 α -adrenergic blocking agents (7.2)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 12/2024

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Phenylephrine Hydrochloride is an alpha-1 adrenergic receptor agonist indicated for

increasing blood pressure in adults with clinically important hypotension resulting primarily from vasodilation, in such settings as septic shock or anesthesia.

2 DOSAGE AND ADMINISTRATION

2.1 General Administration Instructions

Phenylephrine hydrochloride must be diluted before administration as bolus intravenous infusion or continuous intravenous infusion.

Inspect the solution for particulate matter and discoloration prior to administration. The diluted solution should not be held for more than 4 hours at room temperature or for more than 24 hours under refrigerated conditions. Discard any unused portion.

During phenylephrine hydrochloride administration:

- Correct intravascular volume depletion.
- Correct acidosis. Acidosis may reduce the effectiveness of phenylephrine.

2.2 Preparing a 100 mcg/mL Solution for Bolus Intravenous Administration

For bolus intravenous administration, withdraw 10 mg (1 mL of a 10 mg/mL concentration) of phenylephrine hydrochloride injection and dilute with 99 mL of 5% Dextrose Injection, USP or 0.9% Sodium Chloride Injection, USP. This will yield a final concentration of 100 mcg/mL. Withdraw an appropriate dose from the 100 mcg/mL solution prior to bolus intravenous administration.

2.3 Preparing a Solution for Continuous Intravenous Infusion

For continuous intravenous infusion, withdraw 10 mg (1 mL of 10 mg/mL concentration) of phenylephrine hydrochloride injection and add to 500 mL of 5% Dextrose Injection, USP or 0.9% Sodium Chloride Injection, USP (providing a final concentration of 20 mcg/mL).

2.4 Dosing for Perioperative Setting

In adult patients undergoing surgical procedures with either neuraxial anesthesia or general anesthesia:

- 50 mcg to 250 mcg by intravenous bolus administration. The most frequently reported initial bolus dose is 50 mcg or 100 mcg.
- 0.5 mcg/kg/min to 1.4 mcg/kg/min by intravenous continuous infusion, titrated to blood pressure goal.

2.5 Dosing for Septic or Other Vasodilatory Shock

In adult patients with septic or other vasodilatory shock:

- No bolus.
- 0.5 mcg/kg/min to 6 mcg/kg/min by intravenous continuous infusion, titrated to blood pressure goal. Doses above 6 mcg/kg/min do not show significant incremental increase in blood pressure.

2.6 Directions for Dispensing from Pharmacy Bulk Vial

The Pharmacy Bulk Vial is intended for dispensing of single doses to multiple patients in

a pharmacy admixture program and is restricted to the preparation of admixtures for infusion. Each closure shall be penetrated only one time with a suitable sterile transfer device or dispensing set that allows measured dispensing of the contents. The Pharmacy Bulk Vial is to be used only in a suitable work area such as a laminar flow hood (or an equivalent clean air compounding area). Dispensing from a pharmacy bulk vial should be completed within 4 hours after the vial is penetrated.

3 DOSAGE FORMS AND STRENGTHS

Injection: 10 mg/mL phenylephrine hydrochloride is supplied in two vial sizes:

- 1 mL single dose vial (10 mg of phenylephrine hydrochloride per vial)

- 10 mL Pharmacy Bulk Package vial (100 mg of phenylephrine hydrochloride per vial) that will provide ten 1 mL single doses

4 CONTRAINDICATIONS

The use of phenylephrine hydrochloride is contraindicated in patients with:

- Hypersensitivity to it or any of its components

5 WARNINGS AND PRECAUTIONS

5.1 Exacerbation of Angina, Heart Failure, or Pulmonary Arterial Hypertension

Because of its pressor effects, phenylephrine hydrochloride can precipitate angina in patients with severe arteriosclerosis or history of angina, exacerbate underlying heart failure, and increase pulmonary arterial pressure.

5.2 Bradycardia

Phenylephrine hydrochloride can cause severe bradycardia and decreased cardiac output.

5.3 Risk in Patients with Autonomic Dysfunction

The pressor response to adrenergic drugs, including phenylephrine, can be increased in patients with autonomic dysfunction, as may occur with spinal cord injuries.

5.4 Skin and Subcutaneous Necrosis

Extravasation of phenylephrine can cause necrosis or sloughing of tissue.

5.5 Pressor Effect with Concomitant Oxytocic Drugs

Oxytocic drugs potentiate the pressor effect of sympathomimetic pressor amines including phenylephrine hydrochloride [see *Drug Interactions (7.1)*], with the potential for hemorrhagic stroke.

5.6 Allergic Reactions

This product 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 nonasthmatic people.

5.7 Peripheral and Visceral Ischemia

Phenylephrine hydrochloride can cause excessive peripheral and visceral vasoconstriction and ischemia to vital organs, particularly in patients with extensive peripheral vascular disease.

5.8 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 voluntarily 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 disorders: Bradycardia, AV block, ventricular extrasystoles, myocardial ischemia

Gastrointestinal disorders: Nausea, vomiting

General disorders and administrative site conditions: Chest pain, extravasation

Immune system disorders: Sulfite sensitivity

Nervous system disorders: Headache, nervousness, paresthesia, tremor

Psychiatric disorders: Excitability

Respiratory: Pulmonary edema, rales

Skin and subcutaneous tissue disorders: Diaphoresis, pallor, piloerection, 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.
- β -adrenergic blockers
- α -2 adrenergic agonists, such as clonidine
- Steroids
- Tricyclic antidepressants
- Norepinephrine transport inhibitors, such as atomoxetine
- Ergot alkaloids, such as methylergonovine maleate

- Centrally-acting sympatholytic agents, such as guanfacine or reserpine
- Atropine sulfate

7.2 Antagonists

α -adrenergic blocking agents, including phenothiazines (e.g., chlorpromazine) and amiodarone block phenylephrine and are in turn blocked by phenylephrine.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C

Animal reproduction studies have not been conducted with intravenous phenylephrine. It is also not known whether phenylephrine 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.

8.2 Labor and Delivery

The most common maternal adverse reactions reported in studies of phenylephrine use during neuraxial anesthesia during cesarean delivery include nausea and vomiting, which are commonly associated with hypotension, bradycardia, reactive hypertension, and transient arrhythmias. Phenylephrine does not appear to cause a decrease in placental perfusion sufficient to alter either the neonate Apgar scores or blood-gas status.

8.3 Nursing Mothers

It is not known whether this drug is excreted in human milk.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

8.5 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 hepatic 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 OVERDOSAGE

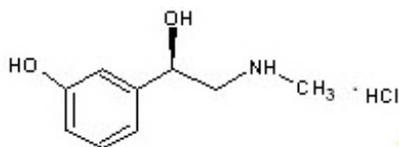
Overdose of phenylephrine hydrochloride can cause a rapid rise in blood pressure.

Symptoms of overdose include headache, vomiting, hypertension, reflex bradycardia, and cardiac arrhythmias including ventricular extrasystoles and ventricular tachycardia, and may cause a sensation of fullness in the head and tingling of the extremities.

Consider using an α -adrenergic antagonist.

11 DESCRIPTION

Phenylephrine hydrochloride is a synthetic sympathomimetic agent in sterile form for parenteral injection. Chemically, phenylephrine hydrochloride is (-)-*m*-Hydroxy- α -[(methylamino)methyl]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. Phenylephrine hydrochloride is sensitive to light.

Phenylephrine Hydrochloride Injection, USP is a clear, colorless, aqueous solution that is essentially free of visible foreign matter. Each mL contains: Phenylephrine Hydrochloride 10 mg; Sodium Chloride 3.5 mg; Sodium Citrate Dihydrate 4 mg; Citric Acid Monohydrate 1 mg; and Sodium Metabisulfite 2 mg in Water for Injection. The pH may be adjusted in the range of 3.0 to 6.5 with Sodium Hydroxide and/or Hydrochloric Acid, if necessary.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Phenylephrine hydrochloride is an α -1 adrenergic receptor agonist.

12.2 Pharmacodynamics

Phenylephrine is the active moiety. Metabolites are inactive at both the α -1 and α -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 phenylephrine hydrochloride administration is rapid and the effect may persist for up to 20 minutes. As mean arterial pressure increases following parenteral doses, vagal activity 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 (340 L) exceeded the body volume by a factor of 5, suggesting a high distribution into certain organ compartments. The average total serum clearance (2095 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. Deamination by monoamino oxidase is the primary metabolic pathway resulting in the formation of the major metabolite (m-hydroxymandelic acid) which accounts for 57% of the total administered dose.

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. Mean arterial blood pressure increases were also observed in two double-blind, active-controlled studies in patients with septic shock.

16 HOW SUPPLIED/STORAGE AND HANDLING

Phenylephrine Hydrochloride Injection, USP, 10 mg/mL, is supplied as follows:

- NDC 72572-571-25: 1 mL single dose vials packaged in cartons containing 25 vials per carton
- NDC 72572-570-10: 10 mL Pharmacy Bulk Package vials packed in cartons containing 10 vials per carton

Store at 20°C to 25°C (68°F to 77°F), excursions permitted to 15°C to 30°C (59°F to 86°F) [See USP Controlled Room Temperature]. Protect from light. Keep covered in carton until time of use. The 1 mL vials are for single use only; the 10 mL vial is a pharmacy bulk package. The diluted solution should not be held for more than 4 hours at room temperature or for more than 24 hours under refrigerated conditions. Discard any unused portion.

17 PATIENT COUNSELING INFORMATION

Inform patients, families, or caregivers that the primary side effect of phenylephrine is hypertension and, rarely, hypertensive crisis. Patients may experience bradycardia (slow heart rate), which in some cases may produce heart block or other cardiac arrhythmias, extra ventricular beats, myocardial ischemia in patients with underlying cardiac disease, and pulmonary edema (fluid in the lungs) or rales. Common, less serious symptoms

include the following:

- chest pain
- skin or tissue damage if the drug leaks out of the venous catheter into the surrounding tissue
- headache, nervousness, tremor, numbness/tingling (paresthesias) in hands or feet
- nausea, vomiting
- excitability, dizziness, sweating, flushing

Manufactured for:

Civica, Inc., Lehi, Utah 84043

Manufactured by:

Hikma Pharmaceuticals USA Inc.

Cherry Hill, NJ 08003

Revised: July 2020

462-884-00

PRINCIPAL DISPLAY PANEL

NDC 72572-571-01

Phenylephrine

Hydrochloride Inj., USP

10 mg/mL

For Intravenous

Use

Dilute before use

Protect from light

1 mL Single Dose Vial



NDC 72572-571-25 Rx Only

**Phenylephrine
Hydrochloride Inj., USP
10 mg/mL**

For Intravenous Use

Dilute before use

25 x 1 mL Single Dose Vials

Discard unused portion

LOT [Yellow Box]
EXP [Yellow Box]

LIGHT SENSITIVE: Keep covered in carton until time of use. To open—Cut seal along dotted line.

NDC 72572-571-25 Rx Only

**Phenylephrine
Hydrochloride Inj., USP
10 mg/mL**

**For Intravenous Use
Dilute before use**

25 x 1 mL Single Dose Vials
Discard unused portion

Each mL contains Phenylephrine Hydrochloride 10 mg; Sodium Chloride 3.5 mg; Sodium Citrate Dihydrate 4 mg; Citric Acid Monohydrate 1 mg; Sodium Metabisulfite 2 mg; Water for Injection q.s. pH adjusted with Sodium Hydroxide and/or Hydrochloric Acid if necessary. pH 3.0-6.5.
Usual Dosage: See package insert.
PROTECT FROM LIGHT. Keep covered in carton until time of use. Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].
Mfd for: Civica, Inc., Lehi, UT 84043
Mfd by: Hikma, Cherry Hill, NJ 08003

CIVICA® 462-881-00

(01)30372572571259

PRINCIPAL DISPLAY PANEL

NDC 72572-570-01 Rx Only

**Phenylephrine
Hydrochloride Inj., USP
100 mg/10 mL (10 mg/mL)**

Pharmacy Bulk Package

Not for Direct Infusion

For Intravenous Use

Must Be Diluted

Protect From Light

10 mL Vial

NDC 72572-570-01 Rx Only

Phenylephrine Hydrochloride Inj., USP

100 mg/10 mL (10 mg/mL)

Pharmacy Bulk Package
Not for Direct Infusion

For Intravenous Use
Must Be Diluted
Protect From Light
10 mL Vial

Each mL contains Phenylephrine Hydrochloride 10 mg; Sodium Chloride 3.5 mg; Sodium Citrate Dihydrate 4 mg; Citric Acid Monohydrate 1 mg; Sodium Metabisulfite 2 mg; Water for Injection q.s. pH adjusted with Sodium Hydroxide and/or Hydrochloric Acid if necessary. pH 3.0-6.5.
Store in carton until time of use.
Store at 20° to 25°C (68° to 77°F) [See USP].
Directions for Use: See Package Insert.
Dispensing from a pharmacy bulk vial should be completed within 4 hours after the vial is penetrated. 462-882-00

Mfd for: Civica, Inc., Lehi, UT 84043
Mfd by: Hikma Pharmaceuticals USA Inc. Cherry Hill, NJ 08003

(01)10372572570012

LOT:
EXP:

NDC 72572-570-10 Rx Only
Phenylephrine Hydrochloride Inj., USP
100 mg/10 mL (10 mg/mL)
Pharmacy Bulk Package
Not for Direct Infusion
For Intravenous Use
Must Be Diluted - Protect From Light
Store in carton until time of use
10 x 10 mL vials

LOT
EXP.

To open - Cut seal along dotted line.

NDC 72572-570-10 Rx Only

Phenylephrine Hydrochloride Inj., USP

100 mg/10 mL (10 mg/mL)

Pharmacy Bulk Package
Not for Direct Infusion

For Intravenous Use
Must Be Diluted — Protect From Light
Store in carton until time of use
10 x 10 mL vials

Each mL contains Phenylephrine Hydrochloride 10 mg; Sodium Chloride 3.5 mg; Sodium Citrate Dihydrate 4 mg; Citric Acid Monohydrate 1 mg; Sodium Metabisulfite 2 mg; Water for Injection q.s. pH adjusted with Sodium Hydroxide and/or Hydrochloric Acid if necessary. pH 3.0-8.5.
Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].
Directions for Use: See Package Insert.
Dispensing from a pharmacy bulk vial should be completed within 4 hours after the vial is penetrated.

Mfd for: Civica, Inc., Lehi, UT 84043
Mfd by: Hikma, Cherry Hill, NJ 08003

462-883-01

CIVICA®

(01)30372572570108

PHENYLEPHRINE HYDROCHLORIDE

phenylephrine hydrochloride injection

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:72572-570
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)		PHENYLEPHRINE HYDROCHLORIDE	10 mg in 1 mL	
Inactive Ingredients				
		Ingredient Name	Strength	
		SODIUM CHLORIDE (UNII: 451W47IQ8X)	3.5 mg in 1 mL	
		TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	4 mg in 1 mL	
		CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	1 mg in 1 mL	
		SODIUM METABISULFITE (UNII: 4VON5FNS3C)	2 mg in 1 mL	
		WATER (UNII: 059QF0KO0R)		
		SODIUM HYDROXIDE (UNII: 55X04QC32I)		
		HYDROCHLORIC ACID (UNII: QTT17582CB)		
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72572-570-10	10 in 1 CARTON	12/02/2020	
1	NDC:72572-570-01	10 mL in 1 VIAL, PHARMACY BULK PACKAGE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NDA	NDA203826	12/02/2020		

PHENYLEPHRINE HYDROCHLORIDE				
phenylephrine hydrochloride injection				
Product Information				
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:72572-571	
Route of Administration	INTRAVENOUS			
Active Ingredient/Active Moiety				
		Ingredient Name	Basis of Strength	Strength
		PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 1 mL
Inactive Ingredients				
		Ingredient Name	Strength	
		SODIUM CHLORIDE (UNII: 451W47IQ8X)	3.5 mg in 1 mL	
		CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	1 mg in 1 mL	

TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	4 mg in 1 mL
WATER (UNII: 059QF0KO0R)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	2 mg in 1 mL
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72572-571-25	25 in 1 CARTON	12/02/2020	
1	NDC:72572-571-01	1 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA203826	12/02/2020	

Labeler - Civica, Inc. (081373942)

Registrant - Hikma Pharmaceuticals USA Inc. (946499746)

Revised: 12/2024

Civica, Inc.