PHENYLEPHRINE HYDROCHLORIDE- phenylephrine hydrochloride injection
IMMPHENTIV- phenylephrine hydrochloride injection
IMMPHENTIV- phenylephrine hydrochloride injectable, liposomal
Hikma Pharmaceuticals USA Inc.

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use IMMPHENTIV® and PHENYLEPHRINE HYDROCHLORIDE safely andeffectively. See full prescribing information for IMMPHENTIV® and PHENYLEPHRINE HYDROCHLORIDE.

IMMPHENTIV® (phenylephrine hydrochloride) injection for intravenous bolus use only
PHENYLEPHRINE HYDROCHLORIDE injection, for intravenous use
Initial U.S. Approval: 2012

RECENT MAJOR CHANGES

Indications and Usage (1)..... 03/2023
Dosage and Administration (2.1, 2.2)..... 03/2023

INDICATIONS AND USAGE

IMMPHENTIV injection 100 mcg/mL 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)
Phenylephrine Hydrochloride Injection 10 mg/mL is alpha-1 adrenergic receptor agonist indicated for increasing blood pressure in adults with clinically important hypotension resulting primarily from vasodilation in the settings of anesthesia and septic shock. (1)

DOSAGE AND ADMINISTRATION

IMMPHENTIV Injection 100 mcg/mL:
- Do NOT dilute prior to administration (2.1)

Dosing for Perioperative Hypotension
- Intravenous bolus administration: 50 mcg to 250 mcg (2.2)
Phenylephrine Hydrochloride Injection 10 mg/mL:
- MUST BE DILUTED before administration. (2.1)
  Dosing for Perioperative Hypotension
  - Intravenous bolus administration: 50 mcg to 250 mcg (2.2)
  - Intravenous continuous infusion: 0.5 mcg/kg/minute to 1.4 mcg/kg/minute titrated to effect (2.2)
  Dosing for Patients with Vasodilatory Shock
  - Intravenous continuous infusion: 0.5 mcg/kg/minute to 6 mcg/kg/minute titrated to effect (2.2)

DOSAGE FORMS AND STRENGTHS

IMMPHENTIV® Injection:
- 500 mcg in 5 mL (100 mcg/mL) of Phenylephrine hydrochloride in a single-dose Ready-To-Use vial (3)
- 1,000 mcg in 10 mL (100 mcg/mL) of Phenylephrine hydrochloride in a single-dose Ready-To-Use vial (3)

Phenylephrine Hydrochloride Injection:
- 10 mg in 1 mL (10 mg/mL) of Phenylephrine hydrochloride in a single-dose vial (3)
- 50 mg in 5 mL (10 mg/mL) of Phenylephrine hydrochloride in a pharmacy bulk package vial (3)
- 100 mg in 10 mL (10 mg/mL) of Phenylephrine hydrochloride in a pharmacy bulk package vial (3)

CONTRAINDICATIONS

- Hypersensitivity to the products or any of their 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 with Phenylephrine Hydrochloride Injection 10 mg/mL: 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: 4/2024

FULL PRESCRIBING INFORMATION: CONTENTS*

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

IMMPHENTIV injection 100 mcg/mL is indicated for increasing blood pressure in adults with clinically important hypotension resulting primarily from vasodilation in the setting of anesthesia.

Phenylephrine Hydrochloride Injection 10 mg/mL is indicated for increasing blood pressure in adults with clinically important hypotension resulting primarily from vasodilation in the settings of anesthesia and septic shock.

2 DOSAGE AND ADMINISTRATION

2.1 General Administration Instructions

Phenylephrine Hydrochloride Injection is injected by bolus intravenous infusion or in dilute solution as a continuous intravenous infusion.

2.2 Preparation of Phenylephrine Hydrochloride Injection

Preparing a 100 mcg/mL Solution for Intravenous Bolus Administration

For intravenous bolus administration, withdraw 10 mg (1 mL of a 10 mg/mL concentration) of Phenylephrine Hydrochloride Injection 10 mg/mL 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 intravenous bolus administration.

Preparing a 20 mcg/mL Solution for Continuous Intravenous Infusion

For continuous intravenous infusion, withdraw 10 mg (1 mL of 10 mg/mL concentration) of phenylephrine hydrochloride injection 10 mg/mL 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).

Directions for Dispensing from Phenylephrine Hydrochloride Injection 10 mg/mL 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.

Dosing for Perioperative Setting

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

- IMMPHENTIV Injection 100 mcg/mL and Phenylephrine Hydrochloride Injection 10 mg/mL (diluted to 100 mcg/mL): 50 mcg to 250 mcg by intravenous bolus administration. The most frequently reported initial bolus dose is 50 mcg or 100 mcg.
- Phenylephrine Hydrochloride Injection 10 mg/mL (diluted to 20 mcg/mL): 0.5 mcg/kg/min to 1.4 mcg/kg/min by intravenous continuous infusion, titrated to blood pressure goal.

Dosing for Septic or Other Vasodilatory Shock (Phenylephrine Hydrochloride Injection 10 mg/mL only)

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.

3 DOSAGE FORMS AND STRENGTHS

IMMPHENTIV® injection, USP: 100 mcg/mL phenylephrine hydrochloride is a clear, colorless, essentially free of visible foreign matter sterile parenteral solution, available in two vial sizes:

- 500 mcg in 5 mL (100 mcg/mL) of Phenylephrine hydrochloride in a single-dose Ready-To-Use vial
- 1,000 mcg in 10 mL (100 mcg/mL) of Phenylephrine hydrochloride in a single-dose Ready-To-Use vial

Phenylephrine Hydrochloride Injection, USP: 10 mg/mL phenylephrine hydrochloride is a clear, colorless, essentially free of visible foreign matter sterile parenteral solution, available in three vial sizes:

- 10 mg in 1 mL (10 mg/mL) of Phenylephrine hydrochloride in a single-dose vial
- 50 mg in 5 mL (10 mg/mL) of Phenylephrine hydrochloride in a pharmacy bulk package vial
- 100 mg in 10 mL (10 mg/mL) of Phenylephrine hydrochloride in a pharmacy bulk package vial

4 CONTRAINDICATIONS

The use of IMMPHENTIV 100 mcg/mL and Phenylephrine Hydrochloride Injection 10 mg/mL is contraindicated in patients with:

- Hypersensitivity to the products or any of their 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

IMMPHENTIV 100 mcg/mL and Phenylephrine Hydrochloride Injection 10 mg/mL 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 IMMPHENTIV 100 mcg/mL and Phenylephrine Hydrochloride Injection 10 mg/mL *[see Drug Interactions (7.1)]*, with the potential for hemorrhagic stroke.

5.6 Allergic Reactions

Phenylephrine Hydrochloride Injection 10 mg/mL 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

IMMPHENTIV 100 mcg/mL and Phenylephrine Hydrochloride Injection 10 mg/mL can cause excessive peripheral and visceral vasoconstriction and ischemia to vital organs, particularly in patients with extensive peripheral vascular disease.

5.8 Renal Toxicity

IMMPHENTIV 100 mcg/mL and Phenylephrine Hydrochloride Injection 10 mg/mL 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

Risk Summary

In animal reproductive and developmental studies, decreased fetal body weights were noted at 0.4 times the human daily dose (HDD) of 10 mg. No malformations were reported, however, an increased incidence of agenesis of the intermediate lobe of the lung, a visceral variation, was reported at levels as low as 0.08 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 to 4% and

15 to 20%, respectively.

Data

Animal Data

No malformations were noted when normotensive pregnant rats were treated with a single daily intravenous bolus dose of 50 mcg, 150 mcg, or 300/200 mcg/kg phenylephrine hydrochloride from Gestation Day 6 to 17 (high dose is 0.3/0.2 times the human daily dose (HDD) of 10 mg/day based on body surface area). Evidence of maternal toxicity, including mortality, was noted at the highest tested dose of 300/200 mcg/kg.

Decreased fetal body weights but no clear treatment-related malformations were reported when normotensive pregnant rabbits were treated with a single daily intravenous bolus dose of 40 mcg, 100 mcg and 200 mcg/kg (0.08, 0.2, and 0.4 times the HDD based on body surface area) phenylephrine hydrochloride from Gestation Day 7 to 19. Maternal toxicity, as manifested by decreased food consumption and body weight gain at all doses. An increased incidence of agenesis of the intermediate lobe of the lung, a visceral variation, was noted in all treatment groups compared to controls.

No adverse effects on the offspring were reported when pregnant rats were treated via a single daily intravenous bolus dose of up to 200 mcg/day phenylephrine hydrochloride (0.2 times the HDD based on body surface area) from Gestation Day 6 to Lactation Day 20.

Pregnancy Category B

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. However, the safety of its use for the management of hypotension associated with neuraxial anesthesia in cesarean deliveries is well established.[71]

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

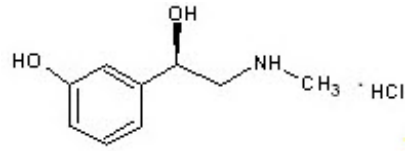
In patients with end stage renal disease (ESRD) undergoing hemodialysis, dose-response data indicates increased responsiveness to phenylephrine. Consider using lower doses of phenylephrine hydrochloride in ESRD patients.

10 OVERDOSAGE

Overdose of IMMPHENTIV 100 mcg/mL and phenylephrine hydrochloride injection 10 mg/mL 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 Injection and IMMPHENTIV® injection contain active pharmaceutical ingredient phenylephrine in the form of hydrochloride salt. Phenylephrine is a synthetic sympathomimetic agent in sterile form for parenteral injection. Phenylephrine hydrochloride chemical name 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.

IMMPHENTIV® Injection, 100 mcg/mL:

IMMPHENTIV®, USP, is a clear, colorless, aqueous solution that is essentially free of visible foreign matter, and Ready-To-Use formulation.

Each mL contains: 100 mcg of Phenylephrine Hydrochloride USP (equivalent to 82 mcg of phenylephrine base), 7.5 mg of Sodium Chloride USP as tonicity agent; 4 mg of Sodium Citrate Dihydrate USP, and 1 mg of Citric Acid Monohydrate USP, as buffering agents, 0.2 mg of Edetate Disodium USP as chelating agent, and Sodium Hydroxide NF and Hydrochloric Acid NF as pH adjusters, in Water for Injection USP. IMMPHENTIV® injection pH range is 3.0 to 6.5.

Phenylephrine Hydrochloride Injection, USP, 10 mg/mL:

Phenylephrine Hydrochloride injection, USP is a clear, colorless, aqueous solution that is essentially free of visible foreign matter. It MUST BE DILUTED before administration as bolus intravenous infusion or continuous intravenous infusion.

Each mL contains: 10 mg of Phenylephrine Hydrochloride (equivalent to 8.2 mg of

phenylephrine base); 3.5 mg of Sodium Chloride USP as tonicity agent; 1 mg of Citric Acid Monohydrate USP and 4 mg of Sodium Citrate Dihydrate USP, as buffering agents; 2 mg of Sodium Metabisulfite USP, as antioxidant, and Sodium Hydroxide NF and Hydrochloric Acid NF, as pH adjusters in Water for Injection. Phenylephrine Hydrochloride injection pH range is 3.0 to 6.5.

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-1and 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.

13 NONCLINICAL 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 dose (HDD) of 10 mg/day based on body surface area) or rats administered approximately 50 mg/kg/day (48-times the HDD based on body surface area comparisons).

Mutagenesis:

Phenylephrine hydrochloride tested negative in the in vitro bacterial reverse mutation assay (S. *typhimurium* strains TA98, TA100, TA1535 and TA1537), the in vitro chromosomal 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 mcg, 100 mcg, or 200 mcg/kg/day (up to 0.2 times HDD of 10 mg/60 kg/day based on body surface area) via single daily bolus injection for 28 days prior to mating to male rats or for 14 days prior to mating through Gestation Day 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. 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

IMMPHENTIV® injection, USP, 100 mcg/mL Ready-to-Use vials is supplied as follows:

- NDC 0641-6245-10: 500 mcg in 5 mL (100 mcg/mL) single-dose vials packaged in cartons containing 10 vials per carton
- NDC 0641-6246-10: 1,000 mcg in 10 mL (100 mcg/mL) single-dose vials packaged 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. Discard any unused portion.

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

- NDC 0641-6142-25: 10 mg in 1 mL fill (10 mg/mL) in 2 mL single-dose vials packaged in cartons containing 25 vials per carton
- NDC 0641-6188-10: 50 mg in 5 mL (10 mg/mL) Pharmacy Bulk Package vials packed in cartons containing 10 vials per carton
- NDC 0641-6189-10: 100 mg in 10 mL (10 mg/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-dose only. Discard any unused portion.

The 5 mL and 10 mL vials are pharmacy bulk packages. The diluted solution should not be held for more than 4 hours at room temperature or for more than 24 hours under refrigerated conditions (2°C – 8°C). 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 by:

Hikma Pharmaceuticals USA Inc.

Berkeley Heights, NJ 07922

Revised: March 2023

462-664-05

PRINCIPAL DISPLAY PANEL

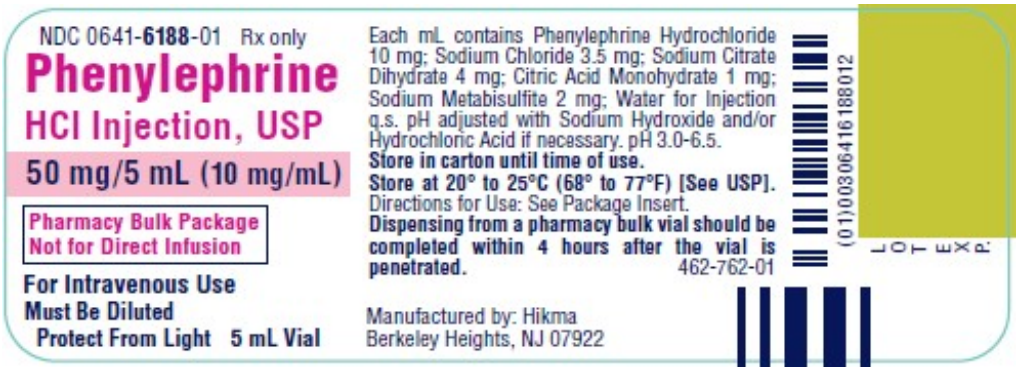
NDC 0641-**6142**-01
Phenylephrine
HCl Injection, USP
10 mg/mL
For Intravenous
Use
Dilute before use
Protect from light
1 mL Single Dose Vial

NDC 0641-**6142**-25 Rx only
Phenylephrine
HCl Injection, USP
10 mg/mL
For Intravenous Use
Dilute before use
25 x 1 mL Single Dose Vials
Discard unused portion

PRINCIPAL DISPLAY PANEL

NDC 0641-6188-01 Rx only

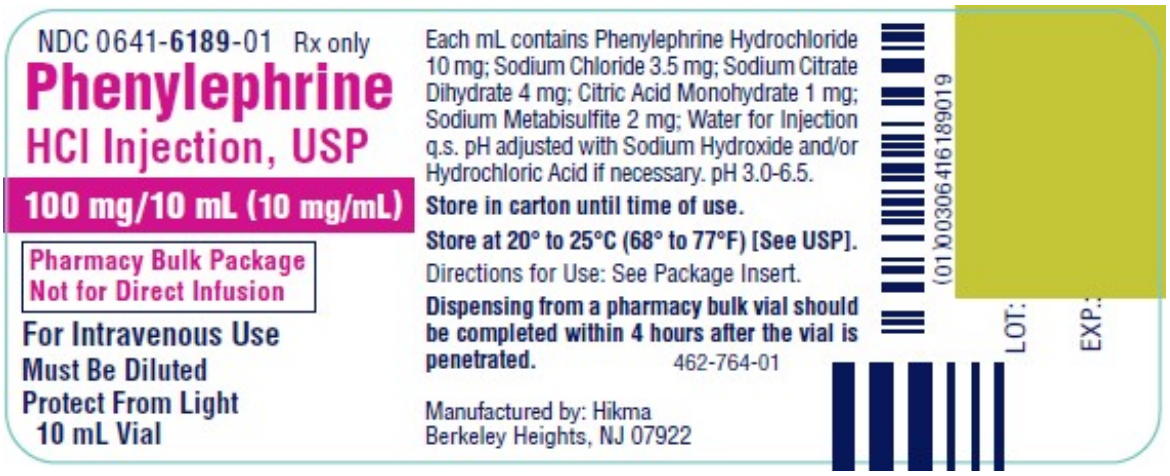
Phenylephrine
HCl Injection, USP
50 mg/5 mL (10 mg/mL)
Pharmacy Bulk Package
Not for Direct Infusion
For Intravenous Use
Must Be Diluted
Protect From Light 5 mL Vial



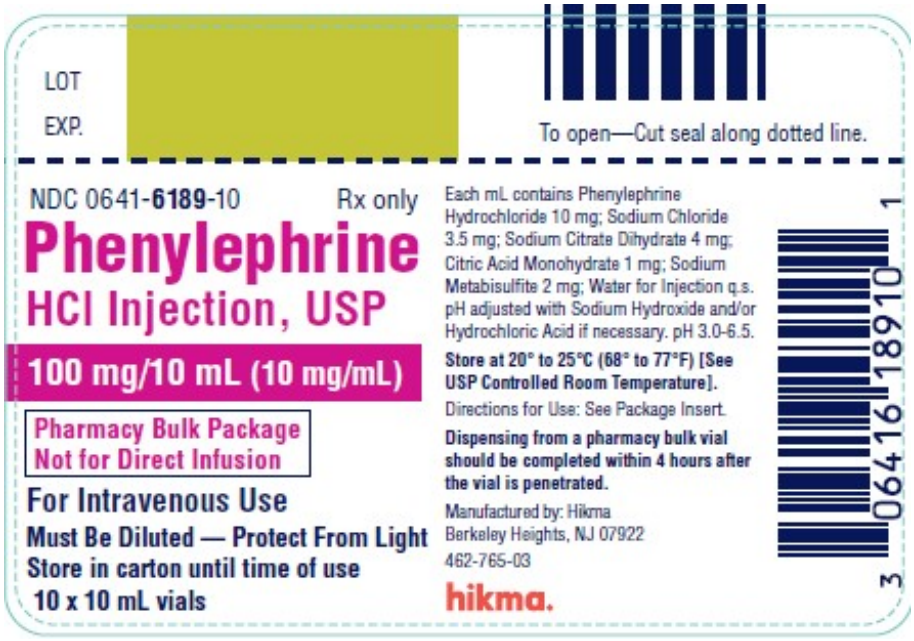
NDC 0641-6188-10 Rx only
Phenylephrine
HCl Injection, USP
50 mg/5 mL (10 mg/mL)
Pharmacy Bulk Package
Not for Direct Infusion
For Intravenous Use
Must Be Diluted - Protect From Light
Store in carton until time of use
10 x 5 mL Vials

PRINCIPAL DISPLAY PANEL

NDC 0641-6189-01 Rx only
Phenylephrine
HCl Injection, 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 0641-6189-10 Rx only
Phenylephrine
HCl Injection, 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



PRINCIPAL DISPLAY PANEL

NDC 0641-6245-01 Rx only

IMMPHENTIV

Phenylephrine HCl Injection, USP

500 mcg per 5 mL (100 mcg/mL)

For Intravenous Use

Ready to Use - Do NOT Dilute

NDC 0641-6245-10 Rx only

IMMPHENTIV

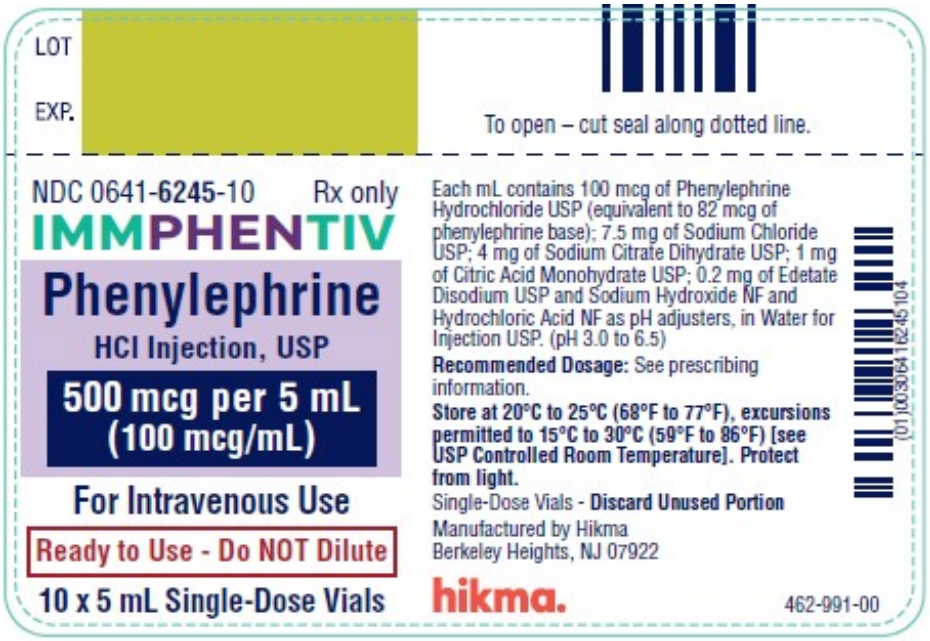
Phenylephrine HCl Injection, USP

500 mcg per 5 mL (100 mcg/mL)

For Intravenous Use

Ready to Use - Do NOT Dilute

10 x 5 mL Single-Dose Vials



PRINCIPAL DISPLAY PANEL

NDC 0641-6246-01 Rx only

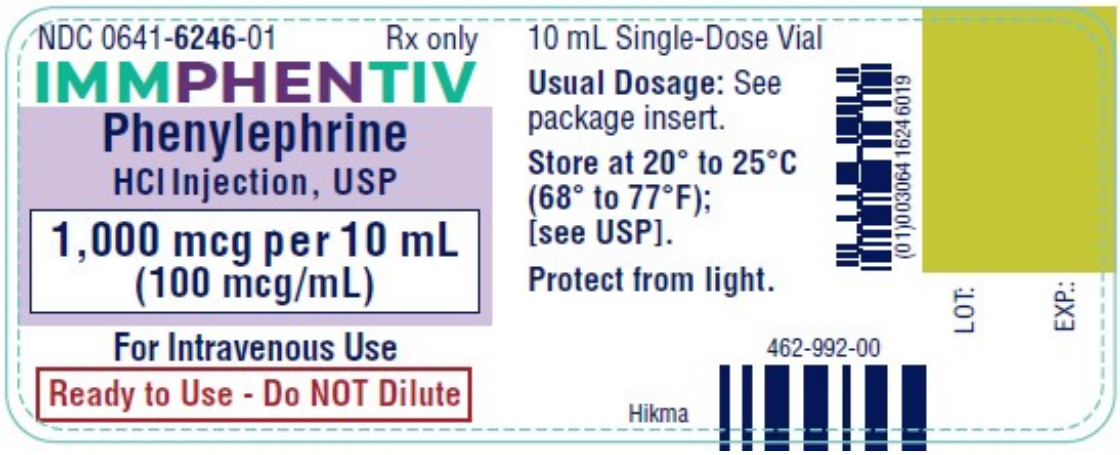
IMMPHENTIV

Phenylephrine HCl Injection, USP

1,000 mcg per 10 mL (100 mcg/mL)

For Intravenous Use

Ready to Use - Do NOT Dilute



NDC 0641-6246-10 Rx only

IMMPHENTIV

Phenylephrine HCl Injection, USP

1,000 mcg per 10 mL (100 mcg/mL)

For Intravenous Use

Ready to Use - Do NOT Dilute

10 x 10 mL Single-Dose Vials

PHENYLEPHRINE HYDROCHLORIDE

phenylephrine hydrochloride injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0641-6142
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:0641-6142-25	25 in 1 CARTON	12/18/2012	
1	NDC:0641-6142-01	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	12/18/2012	

PHENYLEPHRINE HYDROCHLORIDE

phenylephrine hydrochloride injection

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0641-6188
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
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
	NDC:0641			

1	NDC:0641-6188-10	10 in 1 CARTON	06/19/2019	
1	NDC:0641-6188-01	5 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	06/19/2019	

PHENYLEPHRINE HYDROCHLORIDE

phenylephrine hydrochloride injection

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0641-6189
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
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:0641-6189-10	10 in 1 CARTON	06/19/2019	
1	NDC:0641-6189-01	10 mL in 1 VIAL, PHARMACY BULK PACKAGE; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
NDA	NDA203826	06/19/2019	

IMMPHENTIV

phenylephrine hydrochloride injection

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0641-6245
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	100 ug in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	7.5 mg in 1 mL
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	4 mg in 1 mL
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	1 mg in 1 mL
EDETATE DISODIUM (UNII: 7FLD91C86K)	0.2 mg in 1 mL
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0641-6245-10	10 in 1 CARTON	03/09/2023	
1		5 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	03/09/2023	

IMMPHENTIV

phenylephrine hydrochloride injectable, liposomal

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0641-6246
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	100 ug in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	7.5 mg in 1 mL
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	4 mg in 1 mL
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	1 mg in 1 mL
EDETATE DISODIUM (UNII: 7FLD91C86K)	0.2 mg in 1 mL
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0641-6246-10	10 in 1 CARTON	03/09/2023	
1		10 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	03/09/2023	

Labeler - Hikma Pharmaceuticals USA Inc. (946499746)

Establishment

Name	Address	ID/FEI	Business Operations
Hikma Pharmaceuticals USA Inc.		946499746	analysis(0641-6142, 0641-6188, 0641-6189, 0641-6245, 0641-6246) , label(0641-6142, 0641-6188, 0641-6189, 0641-6245, 0641-6246) , manufacture(0641-6142, 0641-6188, 0641-6189, 0641-6245, 0641-6246)