DOPAMINE HYDROCHLORIDE- dopamine hydrochloride injection
ProPharma Distribution

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use DOPamine HYDROCHLORIDE INJECTION safely and effectively. See full prescribing information for DOPamine HYDROCHLORIDE INJECTION.

DOPAMINE HYDROCHLORIDE injection, for intravenous use

Initial U.S. Approval: 1974

INDICATIONS AND USAGE

Dopamine HCl Injection is a catecholamine indicated to improve hemodynamic status in patients in shock. (1)

DOSAGE AND ADMINISTRATION

- Correct hypovolemia, acidosis, and hypoxia prior to use. (2.1)
- Administer in a large vein with an infusion pump preferably in an intensive care setting. (2.1)
- Recommended starting dosage in adults and pediatric patients is 2 to 5 mcg/kg/minute as a continuous intravenous infusion. Titrate in 5 to 10 mcg/kg/minute increments based on hemodynamic response and tolerability, up to not more than 50 mcg/kg/minute. (2.2)
- See the Full Prescribing Information for important preparation instructions and drug incompatibilities. (2.1, 2.3)

DOSAGE FORMS AND STRENGTHS

- The following strengths of Dopamine HCL, USP, are supplied in single-dose vials: (3)
- 200 mg/5 mL (40 mg/mL)
- 400 mg/10 mL (40 mg/mL)
- 400 mg/5 mL (80 mg/mL)
- 800 mg/10 mL (80 mg/mL)

CONTRAINDICATIONS

Dopamine is contraindicated in patients with pheochromocytoma. (4)

WARNINGS AND PRECAUTIONS

- Tissue ischemia: Severe peripheral and visceral vasoconstriction can occur. Address hypovolemia prior to use, monitor extremities, and infuse into large vein. (5.1)
- Cardiac arrhythmias: Monitor closely. (5.2)
- Hypotension after abrupt discontinuation: Gradually reduce infusion rate while expanding blood volume with intravenous fluids. (5.3)
- Severe hypersensitivity reactions due to sodium metabisulfite excipient: May cause anaphylaxis including life-threatening or less severe asthmatic episodes in susceptible individuals. (5.4)

ADVERSE REACTIONS

The most common adverse reaction is localized vasoconstriction due to extravasation. (6)
To report SUSPECTED ADVERSE REACTIONS, contact Hikma Pharmaceuticals USA Inc. at 1-877-845-0689 or FDA at 1-800-FDA-1088 orwww.fda.gov/medwatch.

DRUG INTERACTIONS

- Halogenated anesthetics: Can sensitize the myocardium to the effects of dopamine and can produce ventricular arrhythmias and hypertension. (7)
- MAO inhibitors: Risk of severe hypertension. Reduce recommended Dopamine HCl Injection dosage. (7)
- Tricyclic antidepressants: Risk of hypertension. Monitor blood pressure. (7)
- Vasopressors: Risk of severe hypertension. Monitor blood pressure. (7)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 6/2025

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Dopamine HCl Injection is indicated to improve hemodynamic status in patients in distributive shock or shock due to reduced cardiac output.

2 DOSAGE AND ADMINISTRATION

2.1 Preparation and Administration Instructions

Correct Hypovolemia, Acidosis, and Hypoxia

Address hypovolemia, acidosis, and hypoxia before initiating Dopamine HCl Injection. If patient does not respond to therapy, suspect occult hypovolemia. Acidosis may reduce the effectiveness of dopamine *[see Warnings and Precautions (5.1)]* .

Preparation

For the 40-mg/mL preparation, transfer by aseptic technique the contents containing either 5 mL (200 mg) or 10 mL (400 mg) of Dopamine HCl Injection to either a 250-mL or a 500-mL bottle of one of the sterile intravenous solutions listed below:

- 0.9% Sodium Chloride Injection, USP
- 5% Dextrose Injection, USP
- 5% Dextrose and 0.9% Sodium Chloride Injection, USP
- 5% Dextrose and 0.45% Sodium Chloride Injection, USP
- 5% Dextrose and Lactated Ringer's Injection
- Sodium Lactate Injection, USP 1/6 Molar
- Lactated Ringer's Injection, USP

The resultant dilutions are summarized in the following chart:

Concentration of dopamine hydrochloride	**40 mg/mL**		**80 mg/mL**
Volume of dopamine Hydrochloride Injection, USP	5 mL	10 mL	10 mL
250 mL Bottle of I.V. Solution	800 mcg/mL	1600 mcg/mL	3200 mcg/mL
500 mL Bottle of I.V. Solution	400 mcg/mL	800 mcg/mL	1600 mcg/mL
1000 mL Bottle of I.V. Solution	200 mcg/mL	400 mcg/mL	800 mcg/mL

Dopamine HCl Injection has been found to be stable for 24 hours after dilution in the foregoing intravenous solutions.

Administration

Dopamine HCl Injection is administered (only after dilution) by intravenous infusion.

Administer Dopamine HCl Injection into a large vein *[see Warnings and Precautions (5.1)]* with the use of an infusion pump preferably in an intensive care setting.

Inspect Dopamine HCl Injection for particulate matter and discoloration prior to administration whenever solution and container permit (the solution is clear, practically colorless). Do not administer if the solution is darker or discolored.

Use higher concentration solutions (e.g., 3200 mcg/mL or 1600 mcg/mL strengths) in patients requiring fluid restriction.

Discontinuation

When discontinuing Dopamine HCl Injection, gradually reduce the infusion rate while

expanding blood volume with intravenous fluids *[see Warnings and Precautions (5.3)].*

2.2 Recommended Dosage

The recommended starting dosage in adults and pediatric patients is 2 to 5 mcg/kg/minute as a continuous intravenous infusion *[see Dosage and Administration (2.3)]* . Titrate the infusion rate in increments of 5 to 10 mcg/kg/minute based on hemodynamic response and tolerability, but do not exceed 50 mcg/kg/minute.

Infusion rates may be calculated using the following formula:

$$\textbf{Infusion Rate (mL/hour)} = \frac{\textbf{[Dose (mcg/kg/minute) x Weight (kg) x 60 (minutes/hour)]}}{\textbf{Concentration (mcg/mL)}}$$

Example calculations for infusion rates are as follows:

Example 1:for a 60 kg person at the recommended initial dose of 2 mcg/kg/minute using a 800 mcg/mL concentration, the infusion rate would be as follows:

$$\textbf{Infusion Rate} \text{ (mL/hour)} = \frac{\textbf{[2} \text{ (mcg/kg/minute)} \textbf{ x 60} \text{ (kg)} \textbf{ x 60} \text{ (minutes/hour)]}}{\textbf{800} \text{ (mcg/mL)}} = \textbf{9} \text{ (mL/hour)}$$

Example 2:for a 70 kg person at a dose of 5 mcg/kg/minute using a 1600 mcg/mL concentration, the infusion rate would be as follows:

$$\textbf{Infusion Rate} \text{ (mL/hour)} = \frac{\textbf{[5} \text{ (mcg/kg/minute)} \textbf{ x 70} \text{ (kg)} \textbf{ x 60} \text{ (minutes/hour)]}}{\textbf{1600} \text{ (mcg/mL)}} = \textbf{13.13} \text{ (mL/hour)}$$

2.3 Drug Incompatibilities

Dopamine HCl Injection is incompatible with the following products; therefore, avoid simultaneous administration (through the same infusion set):

- Sodium bicarbonate or other alkalinizing substances, because dopamine is inactivated in alkaline solution
- Blood, because of the risk of pseudoagglutination of red cells
- Iron salts

Do not add additional medications in the diluted infusion solution.

3 DOSAGE FORMS AND STRENGTHS

The following strengths of Dopamine HCL, USP, are supplied in single-dose vials (the

solution is clear practically colorless):

- 200 mg/5 mL (40 mg/mL)
- 400 mg/10 mL (40 mg/mL)
- 400 mg/5 mL (80 mg/mL)
- 800 mg/10 mL (80 mg/mL)

4 CONTRAINDICATIONS

Dopamine is contraindicated in patients with pheochromocytoma.

5 WARNINGS AND PRECAUTIONS

5.1 Tissue Ischemia

Administration of dopamine to patients who are hypotensive from hypovolemia can result in severe peripheral and visceral vasoconstriction, decreased renal perfusion and hypouresis, tissue hypoxia, lactic acidosis, and poor systemic blood flow despite "normal" blood pressure. Address hypovolemia prior to initiating Dopamine HCl Injection *[see Dosage and Administration (2.2)]* .

Gangrene of the extremities has occurred in patients with occlusive vascular disease or who received prolonged or high dose infusions. Monitor for changes to the skin of the extremities in susceptible patients.

Extravasation of Dopamine HCl Injection may cause necrosis and sloughing of surrounding tissue. To reduce the risk of extravasation, infuse into a large vein *[see Dosage and Administration (2.1)]* , check the infusion site frequently for free flow, and monitor for signs of extravasation.

Emergency Treatment of Extravasation

To prevent sloughing and necrosis in areas in which extravasation has occurred, infiltrate the ischemic area as soon as possible, using a syringe with a fine hypodermic needle with:

- 5 to 10 mg of phentolamine mesylate in 10 to 15 mL of 0.9% Sodium Chloride Injection in adults
- 0.1 to 0.2 mg/kg of phentolamine mesylate up to a maximum of 10 mg per dose in pediatric patients.

Sympathetic blockade with phentolamine causes immediate and conspicuous local hyperemic changes if the area is infiltrated within 12 hours.

5.2 Cardiac Arrhythmias

Dopamine may cause arrhythmias. Monitor patients with arrhythmias and treat appropriately.

5.3 Hypotension after Abrupt Discontinuation

Sudden cessation of the infusion may result in marked hypotension. Gradually reduce the infusion rate while expanding blood volume with intravenous fluids.

5.4 Severe Hypersensitivity Reactions due to Sodium Metabisulfite Excipient

Dopamine HCl Injection 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.

6 ADVERSE REACTIONS

The following adverse reactions are described elsewhere in the labeling:

- Tissue Ischemia *[see Warnings and Precautions (5.1)]*
- Cardiac Arrhythmias *[see Warnings and Precautions (5.2)]*
- Hypotension *[see Warnings and Precautions (5.3)]*
- Severe Hypersensitivity Reactions *[see Warnings and Precautions (5.4)]*

The following adverse reactions have been identified during postapproval use of dopamine. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Cardiac Disorders:anginal pain, palpitation

Gastrointestinal Disorders:nausea, vomiting

Metabolism and Nutrition Disorders:azotemia

Nervous System Disorders: headache, anxiety

Respiratory Disorders:dyspnea

Skin and Subcutaneous Tissue Disorders: piloerection

Vascular Disorders: hypertension

7 DRUG INTERACTIONS

See Table 1 for clinically significant drug interactions with dopamine.

Table 1: Clinically Significant Drug Interactions with Dopamine

Halogenated Anesthetics	
Clinical Impact:	Concomitant use may increase cardiac autonomic irritability and can sensitize the myocardium to the action of dopamine which

	may lead to ventricular arrhythmias and hypertension.
Intervention:	Monitor cardiac rhythm.
Examples:	desflurane, enflurane, isoflurane, and sevoflurane.
MAO Inhibitors	
Clinical Impact:	Because dopamine is metabolized by monoamine oxidase (MAO), inhibition of this enzyme prolongs and potentiates the effect of dopamine which may result in severe hypertension and cardiac arrhythmia.
Intervention:	Reduce the recommended starting dosage to no greater than one-tenth (1/10) of the recommended dose in patients who have been treated with MAO inhibitors within two to three weeks prior to the administration of Dopamine HCl Injection.
Examples:	isocarboxazid, phenelzine, tranylcypromine, rasagiline, selegiline, linezolid.
Tricyclic Antidepressants	

Clinical Impact:	Concomitant use may potentiate the cardiovascular effects of dopamine (e.g., hypertension).
Intervention:	Monitor blood pressure.
Examples:	amitriptyline, desipramine, doxepin, imipramine, nortriptyline.
Vasopressors	
Clinical Impact:	Concomitant use may result in severe hypertension.
Intervention:	Monitor blood pressure.
Examples:	norepinephrine, epinephrine, oxytocin.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no human data with dopamine use in pregnant women. There are risks to the mother and fetus from hypotension associated with shock, which can be fatal if left untreated (*see Clinical Considerations*). In animal reproduction studies, adverse developmental outcomes were observed with intravenous dopamine HCl administration in pregnant rats during organogenesis at doses, on a mcg/m ^{2}basis, of one-third the human starting dose of 2 mcg/kg/minute (90 mcg/m ^{2}/minute).

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

Clinical Considerations

Disease-Associated Maternal and/or Embryo/Fetal risk

Hypotension associated with distributive shock, or shock due to reduced cardiac output are medical emergencies in pregnancy which can be fatal if left untreated. Delaying treatment in pregnant women with hypotension associated with distributive shock, or shock due to reduced cardiac output may increase the risk of maternal and fetal morbidity and mortality. Life-sustaining therapy for the pregnant woman should not be

withheld due to potential concerns regarding the effects of dopamine on the fetus.

Labor or Delivery

Vasopressor drugs, including dopamine, may cause severe maternal hypertension when used concomitantly with some oxytocic drugs *[see Drug Interactions (7)]* .

Data

Animal Data

Animal reproduction studies in rats and rabbits at dopamine HCl dosages up to 6 mg/kg/day intravenously (on a mcg/m ^{2}basis, one third and two thirds, respectively, the human starting dosage of 2 mcg/kg/minute) during organogenesis produced no detectable teratogenic or embryotoxic effects, although maternal toxicity consisting of mortalities, decreased body weight gain, and pharmacotoxic signs were observed in rats. In a published study, administration of 10 mg/kg/day dopamine HCl (on a mcg/m ^{2}basis, two-thirds the human starting dosage of 2 mcg/kg/minute) to pregnant rats throughout gestation or for 5 days starting on gestation day 10 or 15 resulted in decreased body weight gain, increased mortality, and slight increase in cataract formation among the offspring.

8.2 Lactation

Risk Summary

There are no data regarding the presence of dopamine in human milk, the effects of dopamine on the breastfed infant, or the effects of the drug on milk production.

8.4 Pediatric Use

Dopamine HCl infusions have been used in pediatric patients from birth through adolescence. Most reports in pediatric patients describe dosing that is similar (on a mcg/kg/minute basis) to that used in adults *[see Dosage and Administration (2.2)]* . Except for vasoconstrictive effects caused by inadvertent infusion of dopamine into the umbilical artery, adverse reactions unique to pediatric patients have not been identified, nor have adverse reactions identified in adults been found to be more common in pediatric patients.

8.5 Geriatric Use

Clinical studies of dopamine 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 start at the low end of the dosing range, reflecting the frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or other drug therapy.

10 OVERDOSAGE

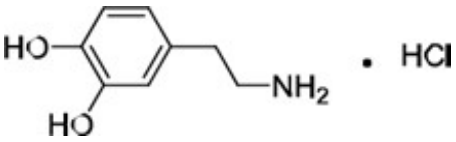
Manifestations of overdosage include excessive blood pressure elevation.

In the case of accidental overdosage, reduce rate of Dopamine HCl Injection administration or temporarily discontinue the dopamine HCl until the overdosage related

adverse reactions resolves. Since dopamine's duration of action is quite short, no additional remedial measures are usually necessary. If these measures fail to resolve the overdosage related adverse reactions, consider using an alpha-adrenergic blocking agent (e.g., phentolamine).

11 DESCRIPTION

Dopamine, a sympathomimetic amine vasopressor, is the naturally occurring immediate precursor of norepinephrine. Dopamine hydrochloride is a white to off-white crystalline powder, which may have a slight odor of hydrochloric acid. It is freely soluble in water and soluble in alcohol. Dopamine HCl is sensitive to alkalies, iron salts, and oxidizing agents. Chemically it is designated as 4-(2-aminoethyl) pyrocatechol hydrochloride, and its molecular formula is $C_8H_{11}NO_2 \cdot HCl$. Dopamine HCl has a molecular weight of 189.64 and it has the following structural formula:



Dopamine (also referred to as 3 hydroxytyramine) is a naturally occurring endogenous catecholamine.

Dopamine hydrochloride injection is a clear, practically colorless, sterile, pyrogen-free, aqueous solution of dopamine HCl for intravenous infusion after dilution. Each milliliter of the 40 mg/mL preparation contains 40 mg of dopamine hydrochloride (equivalent to 32.31 mg of dopamine base). Each milliliter of preparation contains the following: Sodium metabisulfite 9 mg added as an antioxidant; citric acid, anhydrous 10 mg; and sodium citrate, dihydrate 5 mg added as a buffer. May contain additional citric acid and/or sodium citrate for pH adjustment. pH is 3.3 (2.5 to 5.0).

Dopamine must be diluted in an appropriate sterile parenteral solution before intravenous administration *[see Dosage and Administration (2.1)]* .

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Dopamine is a natural catecholamine formed by the decarboxylation of 3,4 dihydroxyphenylalanine (DOPA). It is a precursor to norepinephrine in noradrenergic nerves and is also a neurotransmitter in certain areas of the central nervous system, especially in the nigrostriatal tract, and in a few peripheral sympathetic nerves.

Dopamine elicits its pharmacological action by activating dopamine D1 and D2 receptors, beta 1 receptors and alpha 1 receptors. The activation of different receptors leading to its effects are dependent on dopamine dose.

12.2 Pharmacodynamics

Dopamine's onset of action occurs within five minutes of intravenous administration and

the duration of action is less than about ten minutes. Dopamine effects are dosage-dependent.

- At <5 mcg/kg/minute, dopamine HCl activates dopamine D1 and D2 receptors in the renal, mesenteric, and coronary vasculature causing vasodilation.
- At 5 to 10 mcg/kg/minute, dopamine HCl activates beta-1 receptors enhancing heart rate and contractility.
- At >10 mcg/kg/minute, dopamine HCl activates alpha-1 receptors causing vasoconstriction and increased blood pressure

12.3 Pharmacokinetics

Distribution

Following intravenous administration, dopamine is widely distributed in the body but does not cross the blood-brain barrier to a significant extent.

Elimination

The half-life of dopamine in adults is less than 2 minutes.

Metabolism

About 75% of dopamine is metabolized by monoamine oxidase (MAO) and catechol O-methyl transferase (COMT) in the liver, kidney, and plasma to the inactive compounds homovanillic acid (HVA) and

3,4-dihydroxyphenylacetic acid, and about 25% is metabolized to norepinephrine in the adrenergic nerve terminals.

Excretion

About 80% of dopamine is renally excreted as inactive metabolites within 24 hours. Dopamine is stored in vesicles or diffused back into the plasma.

Specific Populations

Pediatric Patients

The reported clearance rate of dopamine in critically ill infants and pediatric patients ranged from 46 to 168 mL/kg/minute, with the higher values seen in the younger patients. The reported apparent volume of distribution in neonates was 0.6 to 4 L/kg, leading to an elimination half life of 5 to 11 minutes.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

Long term animal studies have not been performed to evaluate the carcinogenic potential of dopamine.

Mutagenesis

Dopamine HCl at doses approaching maximal solubility showed no clear genotoxic potential in the Ames test. Although there was a reproducible dose-dependent increase in the number of revertant colonies with strains TA100 and TA98, both with and without

metabolic activation, the small increase was considered inconclusive evidence of mutagenicity. In the L5178Y TK $^{+/-}$mouse lymphoma assay, dopamine HCl at the highest concentrations used of 750 mcg/mL without metabolic activation, and 3000 mcg/mL with activation, was toxic and associated with increases in mutant frequencies when compared to untreated and solvent controls; at the lower concentrations no increases over controls were noted.

No clear evidence of clastogenic potential was reported in the *in vivo*mouse or male rat bone marrow micronucleus test when the animals were treated intravenously with up to 224 mg/kg and 30 mg/kg of dopamine HCl, respectively.

16 HOW SUPPLIED/STORAGE AND HANDLING

Dopamine Hydrochloride Injection, USP is a clear, colorless to slightly yellow aqueous solution supplied as follows:

Strength Packaged NDC No.

200 mg/5 mL (40 mg/mL) 1 vial 84549-252-25

Store at 20°C to 25°C (68°F to 77°F). [See USP Controlled Room Temperature.]

17 PATIENT COUNSELING INFORMATION

Risk of Tissue Damage

Advise the patient, family, or caregiver to report signs of extravasation urgently *[see Warnings and Precautions (5.1)].*

Manufactured by:

HIKMA FARMACÊUTICA (PORTUGAL), S.A.

Estrada do Rio da Mó, nº 8, 8A e 8B – Fervença, 2705 – 906 Terrugem SNT PORTUGAL

Distributed by:

Hikma Pharmaceuticals USA Inc.

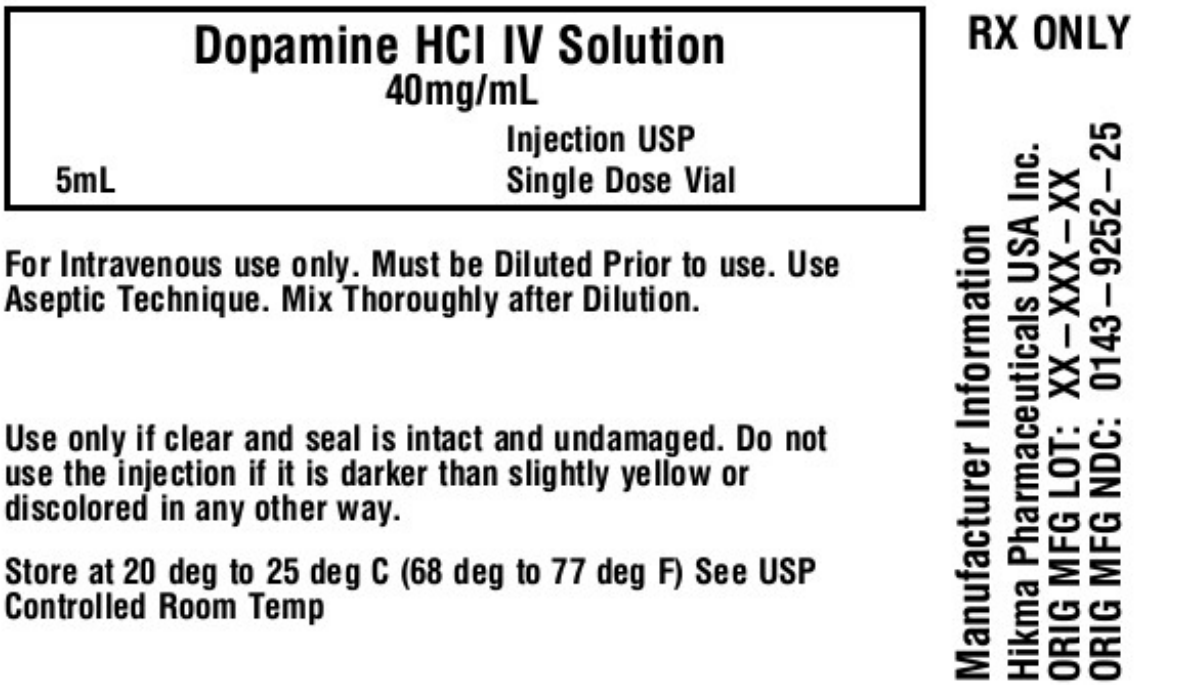
Berkeley Heights, NJ 07922

Revised: April 2024

PIN491-WES/3

PRINCIPAL DISPLAY PANEL

NDC 84549-252-25



DOPAMINE HYDROCHLORIDE

dopamine hydrochloride injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:84549-252(NDC:0143-9252)
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DOPAMINE HYDROCHLORIDE (UNII: 7L3E358N9L) (DOPAMINE - UNII:VTD58H1Z2X)	DOPAMINE HYDROCHLORIDE	40 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	9 mg in 1 mL
SODIUM CITRATE (UNII: 1Q73Q2JULR)	5 mg in 1 mL
CITRIC ACID ACETATE (UNII: DSO12WL7AU)	10 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84549-252-25	5 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product	08/27/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207707	04/11/2018	

Labeler - ProPharma Distribution (883394285)

Establishment

Name	Address	ID/FEI	Business Operations
ProPharma Distribution		883394285	relabel(84549-252) , repack(84549-252)

Revised: 7/2025 ProPharma Distribution